REGISTRATION HANDBOOK

For Pest Control Products Under the
***Pest Control Products Act* and Regulations**

This document provides information on the registration process for pest control products in Canada and general guidance for making registration submissions. For further details on specific registration procedures and data requirements, consult the various guideline documents and regulatory directives published by the Pest Management Regulatory Agency (PMRA), Health Canada, and those previously issued by the Plant Industry Directorate, Agriculture and Agri-Food Canada (AAFC). These AAFC guidelines will remain in effect until they are updated and replaced.

The *Registration Handbook for Pest Control Products Under the Pest Control Products Act* and Regulations (herein referred to as the Registration Handbook) was first published in February 1994, replacing the previous Registration Guidelines. With the reform of the regulatory system in 1995, and the ongoing improvements to PMRA efficiency, many procedures and requirements have been changed or are in the process of being revised. Sections of this Registration Handbook have been revised to reflect these changes.

Although the entire Registration Handbook is issued as an updated document at this time, it continues to be a work in progress since many regulatory procedures are still under review. Further updates of portions of the Registration Handbook will be made as needed. Future updating of the Registration Handbook will be done on a section-by-section or page-by-page basis. It is the responsibility of recipients to keep their copies of the Registration Handbook updated with these revisions. If you would like to receive these updates, please send your request to the Publications Coordinator by fax or by mail at the address below, or by electronic mail at GLEWIS@pmra-arla.hc-sc.gc.ca.

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Part 1
Introduction

1.1 Overview

A complete, high quality submission is an essential first step in the pest control product registration process. The Registration Handbook serves as a detailed reference guide to assist applicants through the registration procedures.

While this document contains excerpts from the *Pest Control Products Act* (PCPA) and Regulations, as well as definitions and interpretations of statutory requirements, it is not a legal document and should be used in conjunction with the complete PCPA and Regulations.

This document consists of 18 parts, including the introduction.

- **Part 2** covers the legislative basis under which pest control products are regulated, and the responsibilities of the federal agency involved in their regulation.
- **Part 3** describes pest control products that are exempt from regulation under the PCPA as well as products that are subject to regulation but are exempt from the registration process.
- **Part 4** deals with research involving pest control products.
- **Parts 5 to 16** provide guidance on registration procedures and data requirements.
- **Part 17** is an alphabetical subject index to assist users in locating appropriate sections or subjects of interest.
- **Part 18** contains appendices that provide a list of regulatory guidelines that have been referenced in the Registration Handbook, a list of Regional Offices of the PMRA, sample application and specification forms, a glossary of terms relating to a product, sample labels, definitions and codes for formulation types, a list of forms referenced in the Registration Handbook, and a list of acronymns used in the Registration Handbook.

1.2 How to Use the Registration Handbook

This document provides comprehensive instructions on certain aspects of registration, e.g., labelling, and serves as a general guidance for others, e.g., data requirements. The PMRA also publishes more detailed guidelines and directives on specific aspects of registration procedures and data requirements. For this information, refer to the list in Appendix A, *List of Documents Referenced in the Registration Handbook.*

Instructions in the Registration Handbook are based on current practices. Policies, procedures and data requirements are subject to development and change. An updated version will be made available on our web site as a downloadable document at http://www.hc-sc.gc.ca/pmra-arla/hndbk-e.html. Applicants are advised to check our web site for the most recent version prior to submitting an application for new or amended registration.

Part 2

Legislative Authority for the Regulation of Pesticides

2.1 The PCPA and Regulations

Pest control products are regulated in Canada under the authority of the PCPA and Regulations. The intent of the legislation is to ensure the acceptability of the risks, merit and value of pest control products used in Canada. This fundamental principle focuses specifically on the protection of human health and the environment and on product performance.

2.2 Products that are Regulated under the PCPA

In the PCPA, a control product is defined as *any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pest*, and includes:

- any compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a control product to which it is added; and

- any active ingredient used for the manufacture of a control product.

The term pest is defined as *any injurious, noxious or troublesome insect, fungus, bacterial organism, virus, weed, rodent or other plant or animal pest, and includes any injurious, noxious or troublesome organic function of a plant or animal.*

As such, products that are regulated under the PCPA cover a wide spectrum. As well as herbicides, fungicides and insecticides, they include biological agents, such as bacteria and viruses that are used to control pests; antimicrobial agents used in oil wells; wood preservation; non-potable water purification systems and material preservation; and growth regulators that control an *injurious, noxious or troublesome organic function of a plant or animal.*

The PCPA and Regulations requires that all pest control products used or imported into Canada be registered unless expressly exempted by regulation from this requirement. This includes both manufacturing-use products (MPs) and all subsequent end-use products (EPs) containing active ingredients.

2.3 Roles and Responsibilities of Government

Regulation of pest control products at the federal level is the responsibility of the Pest Management Regulatory Agency (PMRA), Health Canada.

The PMRA was established in April 1995 in response to the recommendations of the Pesticide Registration Review (PRR) Team. The Multi-stakeholder Review Team was charged with studying and making recommendations to improve the federal pesticide regulatory system. With the transfer of administration of the PCPA from the Minister of Agriculture and Agri-Food to the Minister of Health, the PMRA was established within Health Canada to consolidate the resources and responsibilities for pest management regulation.

The goal of the PMRA is to protect human health and the environment while supporting the competitiveness of agriculture, forestry, other resource sectors and manufacturing. The PMRA is responsible for providing safe access to effective pest management tools while minimizing risks to human and environmental health. The Agency is also dedicated to integrating the principles of sustainability into Canada's pest management regulatory regime.

Structure of the PMRA

Executive Director's Office

- oversees the operation of the PMRA; and
- chairs the Agency Management Committee (AMC), comprised of the directors of all divisions.

Business Line Improvement Section

- responsible for cost recovery policy;
- responsible for business line improvement projects, including electronic environment initiatives;
- coordinates the AMC's agenda;
- co-chairs, with an industry representative, the Economic Management Advisory Committee (EMAC); and
- provides informatics services.

Chief Registrar

- ensures that the PMRA makes integrated, science-based registration decisions;
- manages registration issues;
- investigates registration appeals;
- chairs Science Review Team meetings; and
- provides policy advice.

Submission Management and Information Division

- manages and tracks submissions;
- conducts scientific screenings;
- manages data base;
- publishes regulatory documents;
- provides information services and Access to Information; and
- manages reference centre.

Product Sustainability and Coordination Division

- provides expertise on antimicrobials, fungicides, herbicides, insecticides and other pesticides;
- houses a team of scientific evaluators who conduct efficacy assessments, sustainability evaluations and value assessments for pest control products;
- liaises with industry, provinces, federal departments and other stakeholders on product submissions, research permits, minor uses, product registration and other regulatory issues;
- participates in national and international activities to facilitate harmonization of testing and evaluation procedures; and
- co-ordinates reviews and registration activities, e.g., submissions, renewals, label improvements and re-evaluations.

Health Evaluation Division

- provides expertise on human health hazards, risk assessments and risk mitigation;
- houses a team of scientific evaluators who conduct toxicology evaluation and exposure assessments of pest control products;
- liaises with industry on health issues related to product submissions; and
- participates in national and international activities to facilitate harmonization of testing and evaluation procedures.

Environmental Assessment Division

- provides expertise on environmental hazards, risk assessments and risk mitigation;
- houses a team of scientific evaluators who conduct assessments of the environmental fate and effects of pest control products;
- liaises with industry on environmental issues related to product submissions; and
- participates in national and international activities to facilitate harmonization of testing and evaluation procedures.

Alternative Strategies and Regulatory Affairs Division

- develops policies, programs, and projects related to sustainable pest management;
- coordinates national and international activities;
- directs the development, review and assessment of policies, regulations, programs and legislative amendments;
- develops Integrated Pest Management (IPM) partnership projects with stakeholders;
- liaises with: (1) other federal government departments through the Policy Council and individual Memoranda of Understanding; (2) the provinces through the Federal-Provincial-Territorial Committee on Pesticide Management and Pesticides; and (3) stakeholders through the IPM projects and the Interim Pest Management Advisory Committee;
- houses the Operational Training and Development Program; and
- prepares and implements strategic communications plans for the PMRA.

Compliance and Regional Operations

- enforces the PCPA;
- conducts national pesticide compliance inspections and investigations; and
- represents the PMRA in each province.

Laboratory Services

- provides expertise on the chemistry of pest control products and analytical testing;
- conducts product chemistry evaluations;
- liaises with industry on chemistry issues related to product submissions; and
- directs the provision of laboratory support services.

Management Planning and Coordination Division

- provides financial, administrative, and human resources services.

Responsibilities of the PMRA

The PMRA administers the PCPA for the Federal Minister of Health. The PCPA regulates the use of substances that claim to have a pest control use. The Act also regulates other substances, such as formulants, adjuvants and contaminants, that are contained in pest control products.

Pest control products differ from many other substances that enter the environment in that they are not by-products of a process, but are released intentionally for a specific purpose. Although their biological effects are what make most pest control products valuable to society, these effects can also pose risks to human and environmental health. For this reason, the PCPA and other policies affecting pesticides recognize and consider the environmental and human health risks in addition to the value of each product.

Pest control products have been closely regulated for many years through detailed pre-market assessment and post-registration monitoring activities. The consolidation of pesticide regulatory activities within the PMRA in April 1995 and planned revision of the PCPA are strengthening the life-cycle management of pest control products in Canada. The Agency is fostering sustainability in the context of pest management by facilitating access to alternative products and coordinating the development of long-term, sustainable pest management strategies in a variety of user sectors.

Before making a registration decision regarding a new pest control product, the PMRA conducts the appropriate assessment of the risks and value of the product specific to its proposed use. The value assessment considers whether the use of the product contributes to pest management and whether the application rates are the lowest possible to effectively control the target pest. The risk assessment considers the inherent toxicity, persistence and bioaccumulative nature of the product, while addressing such key concerns as the degree to which humans and the target and non-target environment may be exposed, and the possible health hazards associated with the product. Because pesticides are introduced into the environment at quantifiable rates, the potential short-term impacts of environmental exposures can be closely estimated. For long-term exposure, the PMRA relies on persistence and bioaccumulation data as qualitative indicators as well as on any monitoring data available.

For registered products, ongoing surveillance, advances in analytical methods and improved evaluation processes provide a means to uncover environmental or health concerns, particularly with older products.

Pest control products will be registered if: the data requirements for assessing value and safety have been adequately addressed, the evaluation indicates that the product has merit and value, and the human health and environmental risks associated with its proposed use are acceptable.

The PMRA manages the risks associated with pesticide use in several ways. These include the following:

- setting conditions of registration;
- monitoring compliance with conditions of registration;
- developing label improvement programs that support pest management practices; and
- supporting the development of sustainable pest management strategies that provide a context for registration decisions.

Non-compliance with conditions of registration is a violation of the PCPA and may lead to suspension, cancellation, use restrictions or the phasing out of a pest control product.

For further information about the PMRA, please contact the following:

Pest Management Information Service
Health Canada
A.L. 6606D2
2250 Riverside Drive
Ottawa Ontario K1A 0K9

Tel.: 1-800-267-6315
International Calls: (613) 736-3799
Facsimile: (613) 736-3798

Internet: PMINFOSERV@pmra-arla.hc-sc.gc.ca
http://www.hc-sc.gc.ca/pmra-arla/

Advisory Infrastructure of the PMRA

Arising from the Government's response to the PRR, the federal pest management regulatory system also includes the following infrastructure to provide advice to the PMRA:

- **Economic Management Advisory Committee (EMAC)** - A committee comprising users of pest control products and manufacturers who are impacted economically by decisions of the PMRA. This committee provides strategic advice to the PMRA on ways to improve efficiency and cost effectiveness without compromising health or environmental protection, while at the same time maintaining industry competitiveness.
- **Pest Management Advisory Council (PMAC)** - A multi-stakeholder council has been established to make recommendations on broad strategic directions, management, and

overall priorities for the PMRA; ensuring PMRA programs are consistent with the needs of Canadians within the overall national and global environmental, social and economic context; and act as a forum for advice and for the exchange of views of all key stakeholders on issues affecting the management of pest control products in Canada.

- **Policy Council** - A council consisting of the Executive Director of the PMRA and Assistant Deputy Ministers of the Federal Departments of Agriculture and Agri-Food, Environment, Fisheries and Oceans, Health, Industry, and Natural Resources, with the mandate to: (1) provide a forum for the exchange of advice between departments and the PMRA on policies and programs related to pest management regulation, including pest management, food safety, human health and safety, management of toxic substances in the environment, and the interests of industries that use pest control products; and (2) provide a *single window* for liaison between the PMRA and departments in order to coordinate the flow of information and advice on an ongoing basis.

- **The Federal-Provincial-Territorial Committee on Pest Management and Pesticides** - The Committee comprises two representatives designated by the PMRA, two representatives for each of the provincial governments and one representative for each of the territorial governments as designated by those jurisdictions. Stakeholder involvement will be through Working Groups reporting to the committee and through involvement by invitation at annual meetings. Stakeholder representation could include other government departments, environmental interest groups, industry, user associations, etc. The primary role of the Committee is to: (1) strengthen federal/provincial/territorial relationships in the area of pest management and pesticides; (2) promote information exchange in the area of pest management and pesticides; (3) provide advice and direction to federal, provincial and territorial governments on programs, policies and issues for pesticides with the aim of enhancing sustainable pest control practices; and (4) seek harmonization, where applicable, in programs and policies.

2.4 Other Legislation Regulating Pesticides

In addition to the PCPA, other federal, provincial and municipal enactments may have implications regarding the use of pesticides. For example, the *Food and Drugs Act* (FDA) sets limits for permissible maximum residue levels (MRLs) of pesticides in food; the *Fisheries Act* and the *Migratory Birds Convention Act* provide for the protection of fisheries and migratory birds from substances that pose risks to them and may affect the use of pesticides. As well, the provinces and territories regulate the sale, use and disposal of pesticides within their jurisdictions. They may impose more stringent controls than those applied under the PCPA, but they may not permit the use of products that are not registered or products that are exempt from registration under the Federal Act. In addition, where authorized to do so, municipalities may enact by-laws that affect the use and disposal of pesticides within their boundaries.

Part 3
Exemptions

3.1 Products Exempt From Regulation

The following pest control products are exempt from regulation under the PCPA.

(a) Control products that are subject to the FDA and are used only for these purposes:

- the control of viruses, bacteria or other microorganisms on or in humans or domestic animals;
- the control of arthropods on or in humans, livestock or domestic animals, if the product is administered directly, e.g., orally, sub-cutaneous injection, etc., and not by topical application;
- the control of microorganisms on articles that are intended to come directly into contact with humans or animals for the purpose of preventing or treating disease;
- the control of microorganisms in premises in which food is manufactured, prepared or kept; or
- the preservation of food for humans during cooking or processing.

(b) Control products that are devices unless they are of the type and kind described in Schedule I of the Pest Control Products Regulations (PCPR). See Section 10.4, *Devices*, of the Registration Handbook.

3.2 Products Exempt From Registration

Products that meet the following conditions are subject to regulation under the PCPA but do not require registration:

- a control product that is of a type and kind described in Schedule II of the PCPR;
- a control product used for research purposes under certain conditions. For details, see Part 4, *Research Permits*.

Note: Certain active ingredients that have been accepted for use in control products registered prior to 1984 are presently exempt from registration. After January 1, 1984, an active ingredient used in any new formulated control product is subject to registration.

Part 4
Research Permits

The scientific and technical information needed to evaluate the effectiveness and safety of a pest control product can be provided only by well-documented research. The PCPA provides opportunity for researchers to conduct research under conditions set forth in Section 5(1)(b) of the PCPR.

The conditions for research programs vary, depending on the nature of the product and the type of research involved. In general, research is conducted under a research permit issued by the PMRA. A Notification may suffice under certain conditions of research. The *Application for Research Permit* form and the *Notification of Pesticide Research* form are available from the Agency or the Regional Offices of the PMRA. See Appendix B, *PMRA Regional Offices,* for addresses. For small-scale research under certain conditions, research permits may not be required.

Note: Treated crops from research sites must not be sold for food or feed, and meat (including meat by-products and fat), milk and eggs containing residues as a result of research must not be sold for food unless (1) written authorization has been obtained from the Agency or (2) the residues conform with the existing MRLs as defined in Division 15 of the FDA Regulations.

Guidelines on research programs are available or are being developed for products in the following three categories:

4.1 Chemical Pesticides

Please refer to the regulatory document *Chemical Pesticide Research Permit Guidelines.*

4.2 Pheromones and Other Semiochemicals

Please refer to the regulatory document *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals.*

4.3 Microbial Pest Control Agents

Please refer to the regulatory document *Research Permit Guidelines for Microbial Pest Control Agents.*

Research programs involving products not covered by available guidelines will be considered on a case-by-case basis. For more information, please contact the PMRA Information Service at 1-800-267-6315; and from outside Canada: 1-613-736-3799, for the officers responsible for this information.

Part 5
Applying for Registration - General Procedures

The registration process is designed to evaluate the safety, merit and value of pest control products through pre-sale assessment and registration. The conditions under which each product may be sold and the purposes for which it may be used are established at the time the product is registered. Part 5, *Applying for Registration - General Procedures*, provides general information on how to apply for registration and on how the application is reviewed. For more detailed application procedures and requirements, please refer to the guidelines in the Regulatory document *Organizing and Formatting a Complete Submission for Pest Control Products.*

Note: Information, such as data, formulation, etc., provided to the Agency in support of an application for registration is considered Confidential Business Information (CBI) and will not be disclosed except as provided for under the *Access to Information Act* (ATIA).

5.1 Submitting Applications for Registration

All applications for registration of pest control products must be made to the Submission Management and Information Division, Pest Management Regulatory Agency, Health Canada (A.L. 6605E1), 2250 Riverside Drive, Ottawa, ON K1A 0K9. Submissions are made on a single-product basis, i.e., each product must be documented and applied for individually. However, an application to register a new active ingredient must be accompanied by an application to register a corresponding EP, unless the application is under the Importation for Manufacturing and Export Program (IMEP). See Section 11.6.

A complete submission[1] for registration of a product includes appropriate forms, applicable fees and supporting information as outlined below. Forms are available upon request from the PMRA or Regional Offices of the PMRA. See Appendix B, *PMRA Regional Offices,* for the addresses. Please use only *current* forms; photocopies or outdated forms are not acceptable. The forms must be completed as per individual instructions, then signed and dated.

The PMRA recently announced the availability of electronic fill and print templates for specification, fee and application forms. There are three ways to obtain the electronic templates.

- Contact the Pest Management Regulatory Agency's (PMRA) Publications Coordinator and request to have a diskette mailed to you.

Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2250 Riverside Drive
A.L. 6606D1
Ottawa ON K1A 0K9

Internet: GLEWIS@pmra-arla.hc-sc.gc.ca
http://www.hc-sc.gc.ca/pmra-arla/
Facsimile: (613) 736-3666

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[1] The words *submission* and *application* are used interchangeably in this document.

- E-mail distribution of the templates will be provided upon request. Please provide your e-mail address to the Publications Coordinator, specify which forms you require and your preferred format (Word or WordPerfect).

- You may visit the PMRA's Website at http://www.hc-sc.gc.ca/pmra-arla/qcons3-e.html, where you will find the forms accompanied by downloading and use instructions. You may also view the forms in Adobe Acrobat.

(a) Covering Letter: For all types of applications, it is important to include a covering letter outlining the purpose of the submission with a brief description of the submitted packages. Data should not be included as part of the covering letter.

(b) ***Application for New or Amended Registration*** **Form**: This form is used to apply for all types of registrations, i.e., new, amended or reinstated, except for private labels. (See 11.5.2, *Private Label Products.*) An example of the form is shown as Appendix C.

(c) ***Product Specification*** **form**: This form is required for all submissions involving new products and for any applications for amendments affecting formulation or packaging. The form describes the product recipe and how it is packaged. If the applicant does not know the formulation details because the product will be supplied by another company, the specification form must be completed by the other company and be prominently identified as: "Confidential, Not to Be Released to Registrant". Then the specification form is to be forwarded to the PMRA. This information will remain confidential to the other company; the applicant will not be privy to this information. An example of the form is shown as Appendix D.

For a technical grade of active ingredient (TGAI), the active and impurities must be listed on a weight:weight basis. For EPs, each ingredient in the formulation must be listed with the amount contained expressed as a percentage on a weight:weight basis.

- For each active ingredient, include its registration number under the PCPA and the name and address of your supplier.

- For each non-active ingredient, include its Chemical Abstracts Services (CAS) Number, the name and address of the supplier, and the non-active ingredient's purpose in the formulation, eg., solvent, emulsifier, propellant or perfume.

In the box titled *Physical Characteristics*, provide information to describe your formulation: the bulk density (g/mL) for most powder or granular products, the density (g/L) of liquid formulations, and other information necessary to verify the guarantee and hazard symbols on the label.

The guarantee refers to the amount of active ingredient as stated on the label, and is expressed as follows:

- Identify the active ingredient by its established or common name, see part 7.2.1(e), *Guarantee statement*, or by its chemical name where no common name has been established.

- For dry formulations, calculate the amount of active ingredient as a percentage by weight. Example: if the source of the active ingredient is a technical product or manufacturing concentrate (MA) with a guarantee of 80%, and this source is 10% by weight of the formulation, the guarantee of the formulation is (80%) x (10%) = 8%.

- For liquid or gas formulations, calculate the amount of active ingredient as a percentage by weight, or weight per unit volume. Most liquid agricultural pesticides have the guarantee expressed in g or kg per litre. Example: if the technical product contains 80% of an active ingredient, and constitutes 10% of the formulation, and specific gravity of the formulation is 1.2, the guarantee of the formulation is (80%) x (10%) x 1200 g/L = 96 g/L.

- For other types of formulation, or pest control products other than chemicals, the guarantee is to be expressed in units acceptable to the PMRA.

Note: Historically, the Agency has equated the guarantee with the minimum amount of the active ingredient in the product. However, for purposes of standardization and international harmonization, especially with the U.S. Environmental Protection Agency (EPA), the PMRA adopted the guarantee expression that reflects a *nominal* value. This identifies the typical or nominal concentration of an active ingredient that is expected to be present in a representative sample of a pest control product at the time of its production. The nominal guarantee represents the only acceptable active content expression for new technical active ingredients and associated EPs. See regulatory documents *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products*, and *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*. Currently registered products will be subject to a conversion schedule. For details of the conversion process, please contact the PMRA.

(d) **Letter of Confirmation (LOC)**: For submissions involving new products, new sources of active ingredients in a registered product, transfer of registration, or upgrade in status to the master product or initial product, a letter from the supplier is required to confirm the source of supply of each active ingredient in the product. The registration number of this source material should be quoted in the letter. See Section 5.2.2(d) for a further explanation of the LOC.

(e) **Product Label**: Four (4) hard copies and one electronic copy of a proposed draft label are required for submissions involving new products or label amendments. Refer to Part 7, *Labelling of Products*, for guidance on drafting product labels.

Note: Copies of draft labels are also required as part of the supporting data package.

(f) **Supporting Data**: Scientific data are required for evaluation of the product's effectiveness and the potential for adverse impact on human health and the natural environment. Specific data requirements are detailed in various guidelines available from the PMRA. Data submissions must be organized according to the formats provided in the Regulatory document *Organizing and Formatting a Complete Submission for Pest Control Products.*

Part 0	**Index - Technical Grade of Active Ingredient (TGAI) and End-Use Product (EP)**
Part 1	**Product Label - TGAI and EP**
Part 2	**Product Chemistry - TGAI or Integrated System Product (ISP)**: For more detailed information on chemistry requirements, please refer to the Regulatory document *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product.*
Part 3	**Product Chemistry - End-use Product (EP) or Manufacturing Concentrate (MA)**: For more detailed information on chemistry requirements, please refer to the Regulatory document *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products.*
Part 4	**Toxicology - TGAI or EP**: For information on toxicological studies, refer to the PMRA *Guidelines for Developing a Pesticide Toxicology Data Base.*
Part 5	**Exposure (Occupational and/or Bystander) - EP**
Part 6	**Metabolism/Toxicokinetics Studies - TGAI or EP**
Part 7	**Food, Feed and Tobacco Residues - EP**: Residue data and analytical methodology; for details, refer to the Regulatory document *Residue Chemistry Guidelines.*
Part 8	**Environmental Chemistry and Fate - TGAI and EP**: For details, refer to the PMRA *Guidelines for Determining Environmental Chemistry and Fate of Pesticides.*
Part 9	**Environmental Toxicology - TGAI and EP**: Applicants may submit study protocols for review prior to conducting a study.
Part 10	**Value - EP**: The following guidelines may be useful in preparing a value data package: • *Organizing and Formatting a Complete Submission for Pest Control Products* • *Guidelines for Efficacy Assessment of Chemical Pesticides*

- *Guidelines for Efficacy Assessment of Herbicides and Plant Growth Regulators*
- *Assessment of the Economic Benefits of Pesticides*
- *Guidelines for Efficacy Assessment of Fungicides, Bactericides and Nematicides*

Good Laboratory Practice (GLP)

GLP covers the organizational process and the conditions under which non-clinical laboratory and field studies are planned, conducted, monitored, recorded and reported. GLP is intended to ensure the quality and validity of test data and to improve the international acceptance of data generated in adherence to its principles. The PMRA is implementing GLP following the Organisation for Economic Co-operation and Development's *OECD Principles of Good Laboratory Practice*. The PMRA applies these principles to all testing of pest control products to obtain data on their properties and/or safety with respect to human health or the environment to support an application for registration or a research permit. Studies initiated after the implementation date must be GLP compliant. Failure to provide proof of compliance with GLP may result in the PMRA refusing to consider the study as reliable for purposes of supporting an application for a research permit or registration. For details, please refer to the Regulatory document *Good Laboratory Practice*.

Comprehensive Data Summaries

Effective January 1997, applications for registration of a major new use or new active ingredient must include comprehensive data summaries that have been prepared according to the European Commission (EC) guidelines, i.e., based on the EC Directive Annex II, Tier II format. In addition, submissions must also include an overall summary and assessment document based on the EC Annex II, Tier III model. For details, refer to the regulatory documents *Comprehensive Data Summaries*.

Electronic Submission of Information

In addition to the required number of hard copies, one electronic copy is required for Part 0 (Index), Part 1 (Label) and the comprehensive data summaries. The electronic version must be submitted on a 3.5 inch diskette in valid WordPerfect format unless specified otherwise. If applicants wish to author the information in a different electronic environment, it is the applicant's responsibility to confirm that no text loss or format changes have occurred as a result of the conversion. When submitting a diskette, applicants must also include a letter certifying that the diskette is virus-free and that the information contained in the diskette is a true and accurate duplication of the submitted paper copies. Any diskette found to contain a virus will be returned to the applicant.

(g) ***Fee Form***: The fee per submission varies depending on the type of review required. The fee is specified in the *Fee Form*, which must be completed and submitted with every application. Exemptions are identified in the *Guidance Document on Pest Control*

Product Cost Recovery Fees. A cheque, payable in Canadian funds, to the Receiver General for Canada, with the applicable amount must be included with the application. For information concerning applicable fees, please refer to the PMRA's, *Guidance Document on Pest Control Product Cost Recovery Fees*.

5.2 Completeness of Application

A complete, high-quality submission is a prerequisite for the timely and successful registration of pest control products. Before submitting your application, please ensure that the forms are completed accurately, signed and dated, and that all required components have been included.

The following items are essential in order for your application to be considered complete. Any omissions will result in the submission being returned to the applicant at the applicant's expense.

5.2.1 Step A - Basic Quality Check

Forms and Fees

The first step to a complete application is to ensure that the appropriate forms and fees have been included.

The following items are frequently missing from applications:

(a) A completed *Application for New or Amended Registration* form (the brown form). Please ensure that the form is signed and dated.

(b) A completed, signed and dated, *Product Specification* form (the green form), when required.

(c) Application fees. Indicate in the *Application for New or Amended Registration* form what type of review your product requires, and indicate the appropriate fee in the corresponding box. A completed, signed and dated *Fee Form* must be enclosed with the application. Please enclose only the amount required. For information concerning applicable fees, please refer to the PMRA's, *Guidance Document on Pest Control Product Cost Recovery Fees*.

(d) Four (4) hard copies and one electronic copy of your proposed draft label with all components, including sleeve, box and booklet.

(e) If you are applying for a master copy product, you must first ensure that the master product is already registered. Enter the master product registration number in the Category D section in box 11 of the *Application for New or Amended Registration* form.

(f) If you are applying for a private label product, please ensure that you have recorded the initial product registration number in box 3 of the form, *Application for Registration of a Private Label Product* (based on registered initial product).

5.2.2 Step B - Screening Process

Supporting Documents

When your submission is received, it will be screened for the following:

(a) A detailed covering letter explaining the intent of your application.

(b) All fields on the forms are accurately completed and consistent with the statements in the covering letter.

(c) A *Product Specification* form, if required, to be carefully prepared with emphasis upon the following:

- Is the full name and address of the formulating plant entered?
- Do ingredients add up to 100%?
- Does the guarantee on the form match the guarantee on the label?
- Is the CAS Number provided for each non-active? If not, provide an explanation in the covering letter.
- Are package sizes reasonable for the proposed packaging type and product classification?
- Do registration number(s) and source(s) of active ingredient(s) match those quoted in your LOC(s) of source of supply?

(d) Reference letters, if required by the nature of the submission, include the following:

- Letter of authorization from you as the proposed registrant if another party submits the application on your behalf. The letter should outline the rights and/or privileges the other party has, i.e., signing authority, decision making, etc.
- Letter of authorization from the registrant of the master or initial product if the submission is for a master copy or private label.
- Copy of the *Notification* form from the Bureau of Pharmaceutical Assessment, Therapeutic Products Directorate, Health Canada, indicating

the Drug Identification Number (DIN) for insect repellents with a sun protection factor.

- Letter confirming transfer of ownership from the former registrant since the transfer submission is from the new owner of the product.

- LOC substantiating the source of supply of each active ingredient in the product as required for new products, transfers of registration, changes in source of active, or upgrades in status to the master or initial product. The letter should include all registration numbers and guarantees of the active ingredients involved.

  If the applicant obtains the active ingredient product from an intermediate supplier, a LOC from that supplier is required. In addition, a second letter is required from the registrant of the active ingredient, confirming that the intermediate supplier has access to the registered product. In other words, a chain of LOCs must be provided from the formulated product back to the active ingredient.

(e) Supporting data requirements may vary depending on the nature of the product and the type of registration being applied for. Data are required to support the safety, merit and value of products submitted for registration. Make sure that all relevant data as outlined in Section 5.1(f) are included in the submission and organized according to the regulatory guidelines contained in the Regulatory document *Organizing and Formatting a Complete Submission for Pest Control Products*.

5.3 Processing Application for Registration

The following is a brief outline of the proposed submission management process. For details, please refer to the Regulatory document *Management of Submissions Policy*, and the regulatory guidelines *Organizing and Formatting a Complete Submission for Pest Control Products*.

5.3.1 Verification

Within seven days of receipt, all submissions are verified by the Submission Control Unit to ensure that fees, forms, labels and required information have been provided. Deficiencies will result in the submission being returned to the applicant at the applicant's expense. An applicant whose submission is verified is provided with an acknowledgement card that includes the submission number. This number should appear on all correspondence to the Agency dealing with that submission. Once verified, submissions are forwarded to the Submission Screening Section for screening.

5.3.2 Screening

Submissions are screened for acceptability based on current data requirements. Screening documents are provided to applicants upon request. Submissions are screened within 45 days of receipt by the Submission Screening Section. If no deficiencies are identified, the submission is accepted and forwarded to the appropriate science divisions for review. If deficiencies are identified, the applicant will be notified and generally has 45 calendar days to submit all of the requested information. There are no reminders. If there is no response or if the response is incomplete or inadequate, the submission is withdrawn and returned to the applicant at the applicant's expense. The submission number is no longer valid. A submission that has been withdrawn may be submitted as a new submission.

5.3.3 Submission Categories and Required Review

Depending on the nature of the proposed registration and the review process required, applications for registration generally fall into one of five submission categories:

Category A submissions include new TGAIs or ISPs and their related EPs, major new uses (for new use-site categories, see the Regulatory document *Organizing and Formatting a Complete Submission for Pest Control Products)*, User Requested Minor Use Registrations (URMURs) and the establishment of MRLs for previously unassessed TGAIs. An application to register a new active ingredient must be accompanied by an application to register a related EP(s). Category A submissions require either full or substantial data packages.

Category B submissions require evaluation by one or more science divisions based on a change within a use-site category. These include changes in product chemistry, such as sources and specifications for a TGAI, and the following changes for an EP or a MA: guarantee, form of active ingredients, formulation and new combinations of TGAIs. Category B submissions also include label changes resulting from changes in the following: application rates, timing, method, level of control, tank mixtures, pests, precautionary statements, and product classification. Category B submissions also include conversion or extension of temporary registration, and additional import MRLs for previously assessed TGAIs.

Category C submissions include applications that do not require supporting data for new or amended registrations requiring minor label and/or formulation reviews, e.g., product registrations based on precedent.

Category D submissions include applications for new or amended registrations representing special programs, such as the IMEP, Pesticide Own Use Import (OUI), Master Copy, Private Label, and User-Requested Minor Use Label Expansion (URMULE). The current versions of regulatory documents concerning these special programs are listed in Appendix A, *List of Documents Referenced in the Registration Handbook.*

Category E submissions include Research Permits for new active ingredients, new use of registered active ingredients, and notifications that are required for field research carried out in Canada. Exemptions from data requirements are based on the size and location of treated areas.

Reviews will be conducted following the interim performance standards for submission categories as outlined in the Regulatory document *Management of Submissions Policy*.

The review of the submission is coordinated by the Product Sustainability and Coordination Division (PSCD) to ensure that performance standards are met. The review of data is conducted by the appropriate science divisions and includes the preparation of a Proposed Regulatory Decision Document (PRDD), when required.

5.3.4 Proposed Regulatory Decision Document (PRDD)

Based on a full review of the application and the supporting information, PRDDs are produced for public consultation for all new active ingredients and some major new uses of currently registered pesticides. The consultation period for all PRDDs is normally 45 days from the date of publication. The comments received during the consultation period are assessed, and the final decision is made within 45 days from the end of the comment period.

5.3.5 Decision

The applicant will be notified of the decision. If the proposed registration is acceptable, the applicant receives a consolidated letter of intent to register from the Chief Registrar, outlining the regulatory decision.

5.3.6 Final Label Review

The applicant has 365 days to submit a final label in response to the letter of intent to register. Approval of the final label and issuance of the Certificate of Registration takes place within 45 days of the receipt of the final label. If the final label has errors that could compromise human and environmental health or safety, or product performance, the applicant is asked to change the label and is given a further 30 days. The Agency then has 30 days to complete the label review and issue the registration certificate.

The Certificate of Registration is issued and the product register is updated.

Note: Until the certificate has been issued, sale of the product is a violation of the PCPA. Refer to 7.11, *Final Labels*, for further instructions on final labels.

5.3.7 Product Register

A product file or register is maintained for each registered product. Essential elements of the product file include the most recently approved printed label, the *Product Specification* form, and the Certificate of Registration.

5.4 Foreign Applicants and Canadian Agents

An applicant not residing in Canada must have a Canadian agent. The name and address of the Canadian agent must be on the application form. Under the authority of the PCPA, a regulatory notice issued to a foreign applicant is considered to have been received by him/her once it has been received by his/her Canadian agent.

Part 6
Product Classification

6.1 Identification of Product Classes

The primary consideration in classifying control products is the use for which the product is intended. Based on intended use and potential hazards, EPs are classified into three classes: DOMESTIC, COMMERCIAL, and RESTRICTED. Where the control products are used for the purpose of manufacturing only, they are of the MANUFACTURING classification. The front panel of the label for a control product must show the appropriate product class, as described below.

DOMESTIC

This is the classification for products marketed to consumers for use in and around a dwelling. The intent of the DOMESTIC classification is to provide consumers with relatively safe products for such uses as, insect and rodent control within the home, weed control in lawns and gardens, and swimming pool disinfection.

COMMERCIAL

This is the classification for products marketed for general use in the commercial activities specified on the label. More descriptive words such as AGRICULTURAL or INDUSTRIAL may also be used. The intent of the COMMERCIAL classification is to provide operators engaged in farming or commercial pest control operations with products that can be used safely and efficaciously in their particular business.

RESTRICTED

This is the classification for products with additional limitations respecting the display, distribution, use, or operator qualifications. These must be specified on the label because of safety concerns for humans, plants, animals or the environment. The intent of the RESTRICTED classification is to limit the availability of relatively hazardous products to situations where they can be used safely. Control products may be considered more hazardous because of inherent toxicity or intended use in environmentally sensitive areas. Such areas include most forestry and aquatic applications of control products.

MANUFACTURING

This is the classification for a technical active ingredient, a MA or an ISP. See Appendix E, *Glossary of Terms Relating to a Product*. In other words, the purpose is to manufacture, formulate or repackage into EPs. It is possible for a product to be sold both for end-use and for manufacturing purposes. In such cases, one label suffices for both markets, and the label must bear the appropriate classification for the end-use market.

6.2 Safety Criteria for Classes

In addition to the primary consideration of use, each of the end-use classes, i.e., DOMESTIC, COMMERCIAL, and RESTRICTED, can also be characterized by individual toxicological, environmental, and packaging criteria. Because there is an ascending degree of hazard associated with each category from DOMESTIC to RESTRICTED, a registered control product can only be classified into one of these categories.

DOMESTIC CLASS, for products meeting all of the following criteria:

- acute oral LD_{50} is over 500 mg/kg;
- acute dermal LD_{50} is over 1000 mg/kg;
- no special precautions or equipment required for inhalation hazard;
- product and containers can be safely discarded by placing in household garbage; and
- package sizes limited to amounts that can be safely stored and used by consumers in a single season, where applicable.

COMMERCIAL CLASS, for products meeting both of the following criteria:

- acute oral LD_{50} is over 50 mg/kg; and
- acute dermal LD_{50} is over 100 mg/kg.

RESTRICTED CLASS, for products meeting at least one of the following criteria:

- acute oral LD_{50} is less than 50 mg/kg;
- acute dermal LD_{50} is less than 100 mg/kg;
- significant environmental risks; or
- control products used in aquatic or forestry situations.

6.3 Restricted Uses of Commercial Products

Some products with inherent characteristics that justify COMMERCIAL classification may potentially have RESTRICTED uses.

The following alternatives may be considered by registrants:

- separate registration, i.e., one COMMERCIAL product and one RESTRICTED product; or
- identify the RESTRICTED use in a box on the COMMERCIAL class label, with a description of the additional essential conditions that are imposed.

The intent of the second alternative is to allow the identification of RESTRICTED uses on the secondary panel of a COMMERCIAL class product label in the manner prescribed by Section 34 of the PCPR. A "NATURE OF RESTRICTION" statement must appear directly under the heading, "RESTRICTED USES". For further information, see Section 7.5, *Special Label Requirements for Restricted Uses*.

The acceptability of a RESTRICTED use on a COMMERCIAL class product label will be determined by the PMRA.

Part 7
Labelling of Products

The following guidelines are designed to explain labelling requirements for products and devices that fall under the jurisdiction of the PCPA. The detailed instructions are intended to provide comprehensive guidance for drafting practical and informative labels. Note, however, that the draft label is subject to modification, and written acceptance is required before the printing of a final label. Refer to Section 27 of the PCPR for further details.

Sample labels for DOMESTIC, COMMERCIAL and RESTRICTED products are provided in Appendices F, G and H respectively.

7.1 Definitions

Label: Includes stickers, tags, seals, leaflets, brochures and wrappers applied on or attached to the control product package, and on which is written, printed, stencilled, lithographed or embossed any graphic matter that is descriptive or relates to the control product in any fashion.

Display Panel: That part of the label applied on or attached to the control product package, but not including any leaflet or brochure that may accompany the product. The display panel consists of one principal display panel and at least one secondary display panel. In some situations, the principal and secondary display panels may be combined.

Principal Display Panel: That part of a label displayed or visible under normal conditions of display or use. In general, the area of the principal display panel is as outlined below:

- Rectangular-shaped containers: the area of one side;
- Cylindrical-shaped containers: forty per cent of the area obtained by multiplying the circumference by the height of the container;
- Bags: the area of one side of the unfolded bag;
- Products mounted on an accompanying display card: the surface of that side of the card on which the product is mounted;
- Lid of the container as the principal display surface: the area of the entire top surface of the lid; or
- Containers shaped other than those described above: forty per cent of the total surface of the container, unless the container has an obvious principal display panel, in which case that total area should be used.

For large containers, not all of the area described above may be required for the principal display panel. In such cases, the principal display panel will be as large as required to contain the necessary information.

Secondary Display Panel: That part of a label other than the principal display panel.

7.2 General Labelling Requirements for Pest Control Products

Language: The language used on control product labels may be either English, French, or both. In the case of bilingual labels, all information that appears must be in both languages and must be treated equally as to print size and formatting.

Print Legibility: The print for all information on labels must be of a size, type, and colour to be easily read by people with normal eyesight.

Capital Letters and Graphic Devices: Certain label headings and instructions must appear in capital letters. Other graphic devices, such as bold-face type, may be used as long as the specified headings and instructions are distinct from the surrounding label copy.

Control products that fall under the jurisdiction of the PCPA must bear a label in the following form:

7.2.1 Principal Display Panel

(a) Product name

The name should be specific to the product and be descriptive of its physical form and purpose. It may include a distinctive brand or trademark.

Product names that are confusing, misleading or make exaggerated claims will be rejected.

(b) Class designation

The class to which a product has been assigned must be indicated in capital letters as follows:

DOMESTIC

COMMERCIAL*

RESTRICTED

MANUFACTURING

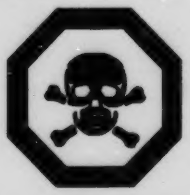
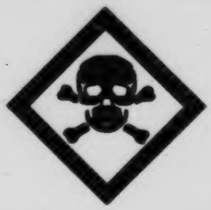
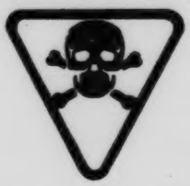
* More descriptive terms, such as AGRICULTURAL, INDUSTRIAL, and INSTITUTIONAL, can be used to define the commercial activities on the label.

(c) Precautionary symbols

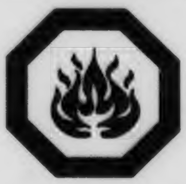
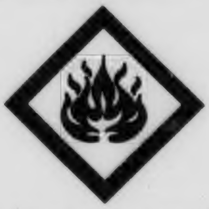
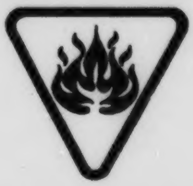
The following precautionary symbols and signal words must appear on the product label, if the product has these specific properties:

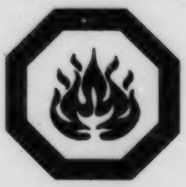
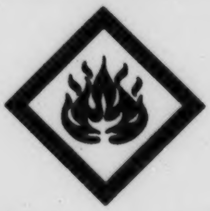
Note: Some of the criteria for acute hazard labelling have been revised to reflect revisions made to internationally recognized protocols for acute testing, or to refine and elaborate on areas previously not well addressed. The revised criteria have been implemented over the course of several years and reflect current operational practices for new products. Until further notice, for currently registered products, the registrants may apply to revise the product labels based on the revised criteria for hazard labelling, at their convenience.

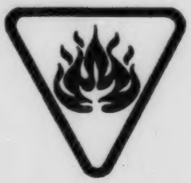
POISON HAZARD

Products with any of the following properties	Require this warning symbol and signal words
- acute oral LD$_{50}$ less than 500 mg/kg bw - acute dermal LD$_{50}$ less than 500 mg/kg bw - acute inhalation LC$_{50}$ less than 0.05 mg/L - contains 10% or more petroleum distillate and is classified "DOMESTIC" (except for pressurized products) - contains 10% or more pine oil	 DANGER POISON
- acute oral LD$_{50}$ 500-1000 mg/kg bw - acute dermal LD$_{50}$ 500-1000 mg/kg bw - acute inhalation LC$_{50}$ 0.05-0.5 mg/L - contains 1% to 10% pine oil	 WARNING POISON
- acute oral LD$_{50}$ 1000-2000 mg/kg bw - acute dermal LD$_{50}$ 1000-2000 mg/kg bw - acute inhalation LC$_{50}$ 0.5-2 mg/L	 CAUTION POISON

FLAMMABILITY HAZARD

Non-pressurized products with the following properties	Require this warning symbol and signal words
- flashpoint less than -6°C	 DANGER EXTREMELY FLAMMABLE
- flashpoint from -6°C to 10°C	 WARNING FLAMMABLE
- flashpoint from 10°C to 27°C	 CAUTION FLAMMABLE

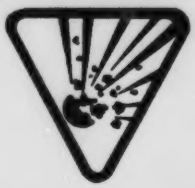
Pressurized products with the following properties	Require this warning symbol and signal words
- ignition of the spray takes place and forms a flame projection of 45 cm or more at full valve opening, or flashback to the container occurs at any valve opening	 DANGER EXTREMELY FLAMMABLE
- ignition of the spray takes place and forms a flame projection of 15 to 45 cm at full valve opening	 WARNING FLAMMABLE

- ignition of the spray takes place and forms a flame projection of less than 15 cm at full valve opening	 CAUTION FLAMMABLE

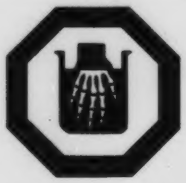
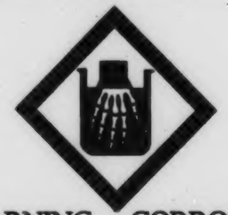
For any pressurized product exhibiting a flame projection, the statement "Do not use in presence of open flame or spark" is required under the "Precautions" heading on the secondary panel of the label. All pressurized products require a statement regarding a maximum storage temperature.

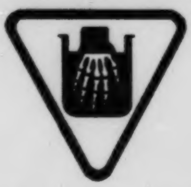
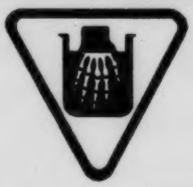
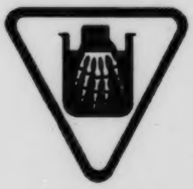
Products exhibiting a flame projection of greater than 90 cm are not generally acceptable for registration under the PCPA. Only those products that are designed to be used at a distance of greater than 90 cm from the target will be exempt from this limitation.

EXPLOSIVE HAZARD

Pressurized products with explosive hazard	Require this warning symbol and signal words
- all pressurized products	 CAUTION EXPLOSIVE

CORROSIVE HAZARD

Products with any of the following properties	Require this warning symbol and signal words
- contains 10% or more mineral acids or alkali materials - contains 20% or more organic acids	 DANGER CORROSIVE
- contains 5-10% mineral acids or alkali materials - contains 5-20% organic acids - liquids containing 10% or more available chlorine - pH less than or equal to 0.5, or greater than or equal to 13.5	 WARNING CORROSIVE

Products with any of the following properties	Require this warning symbol and signal words
- contains 1-5% mineral acids or alkali materials - contains 1-5% organic acids - solids containing over 1% available chlorine - pH between 0.5-2.5 or 11.5-13.5	 CAUTION CORROSIVE
- liquid products containing more than 4% and less than 10% available chlorine will require the signal word CAUTION to indicate the degree of hazard, plus the signal word IRRITANT to indicate the nature of the primary hazard, plus the corrosive symbol superimposed on the caution symbol	 CAUTION IRRITANT
- liquid products containing greater than 1% and less than 4% available chlorine will require only the signal word CAUTION to indicate the degree of hazard, plus the corrosive symbol superimposed on the caution symbol	 CAUTION

EYE HAZARD

Products with any of the following properties	Require these key signal words
- severely to extremely irritating (including irreversibility)	DANGER - CORROSIVE TO EYES
- moderately irritating	WARNING - EYE IRRITANT
- mildly irritating	CAUTION - EYE IRRITANT

SKIN HAZARD

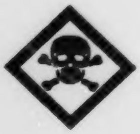
Products with any of the following properties	Require these key signal words
- severely to extremely irritating	DANGER - SKIN IRRITANT
- moderately irritating	WARNING - SKIN IRRITANT
- mildly irritating	CAUTION - SKIN IRRITANT

Where there is conflicting information between corrosive hazard, based on physico-chemical properties, and skin/eye hazard, based on biological response, consult with the PMRA for appropriate labelling.

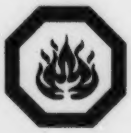
MULTIPLE SYMBOLS: Where more than one precautionary symbol is required on the label, only the most severe signal word is required, and all of the hazard identifying words.

Example

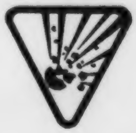
DANGER



POISON



FLAMMABLE



EXPLOSIVE

(d) Directions to read the label

"READ THE LABEL BEFORE USING" must appear in capital letters.

When use directions are provided in the format of a brochure or leaflet, the statement can be modified to: "READ THE LABEL AND ATTACHED BROCHURE (or LEAFLET) BEFORE USING".

(e) Guarantee statement

Historically, the Agency has equated the guarantee with the minimum amount of the active ingredient in the product. However, for purposes of standardization and international harmonization, especially with the U.S. EPA, the PMRA adopted the guarantee expression that reflects a *nominal* value. This identifies the typical or nominal concentration of an active ingredient that is expected to be present in a representative sample of a pest control product at the time of its production. The nominal guarantee represents the only acceptable active content expression for new technical active ingredients and associated EPs - see the regulatory documents *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products*, and *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*. Currently registered products will be subject to a conversion schedule. For details of the conversion process, please contact the PMRA. Please observe the following in labelling:

- GUARANTEE: Must appear in capital letters.
- Active ingredients: Each active ingredient is to be identified by its established or common name,* or by its chemical name*, where no common name has been established.

*** Note:** Common names are based on those established by the International Standards Organization (ISO). Chemical names should follow those of the International Union of Pure and Applied Chemistry (IUPAC).

- Amount of active ingredients: For liquid products, express amounts as percentage by weight, weight per unit volume, or both, as may be required.

  Liquid agricultural pesticides in containers of one litre or more should have the guarantee expressed in grams (g) or kilograms (kg) per litre.

  For a dust, wettable powder, or other dry formulations, express the guarantee as a percentage by weight.

  For other types of formulation, the guarantee will be expressed in units acceptable to the PMRA.

Note: For EPs containing formulants appearing on U.S. EPA Inerts List 1, the name of the List 1 formulant and the percentage at which it is present must be disclosed on the label, under the guarantee statement, using the following statement: "This product contains x% of [common name of the formulant] which has been shown to be of toxicological concern."

(f) Registration Number

The registration number must be specified in capital letters as follows:

"REGISTRATION NO. xxxxx PEST CONTROL PRODUCTS ACT".

Due to limitations of container size, the registration number on DOMESTIC class products may be abbreviated to: "REG. NO. xxxxx P.C.P. ACT".

(g) Net contents

The net contents of the package of a control product must be expressed in metric units, as follows (Imperial units may appear in brackets after the metric units):

- Liquid products: For volume less than 1000 millilitres, use millilitres (mL); for 500 millilitres, the term 0.5 litre (L) may be used.
- For volume of 1000 millilitres or more, use litres (L).
- Dry products: Mass less than 1000 grams, use grams (g); for 500 grams, 0.5 kilogram (kg) may be used.
- Mass of 1000 grams or more, use kilograms (kg) to three significant figures, e.g., 1.44 kg, 10.5 kg; full unit figures, such as 1 kg, 5 kg, and 10 kg are considered to represent 1.00 kg, 5.00 kg, and 10.0 kg, respectively.
- Semi-solid or viscous products: State in terms of either weight or volume as outlined above.

- Pressurized products: State in terms of weight inclusive of the propellant, expressed in grams.
- Other types of products: Where the nature of the product does not lend itself to net content statements as outlined above, the contents will be expressed in a manner acceptable to the PMRA.

(h) Name and address of registrant

The name and postal address of the registrant must be shown. The name and postal address of the Canadian agent are also required. Canadian agents for U.S. registrants may be exempted. The name and address of the distributor may also appear on the label. A telephone number must appear for TGAIs, MAs and ISPs.

(i) Child hazard warning statement

The phrase "KEEP OUT OF REACH OF CHILDREN" is required on all Domestic class products on the principal display panel. The child hazard warning may be omitted from the labels of Manufacturing and Industrial products. All other products should bear the statement "KEEP OUT OF REACH OF CHILDREN" on the secondary display panel under the Precautions.

7.2.2 Secondary Display Panel

(a) Directions for use

Complete information on application rates, directions for use and use limitations must be included on this panel.

Where applicable, common names of the pests should conform to those in the following publications:

(1) Alex, J.F., R. Cayonette and G.A. Mulligan. 1980. *Common and Botanical Names of Weeds in Canada.* Agriculture Canada, Research Branch, Publication No. 1397. Ottawa, Ontario.

(2) Anon. 1992. *Names of Plant Diseases in Canada.* Que. Soc. Protection of Plants. Sainte-Foy, Québec.

(3) Banfield, A.W.F. 1974. *The Mammals of Canada.* University Press. Toronto, Ontario.

(4) Benoit, P. 1985. *Insect Names in Canada.* 5th edition. Canadian Forestry Service, Laurentian Forest Research Centre. Sainte-Foy, Québec [A diskette version, edited by E.M. Belton and D.C. Eidt, 1993, is available from the Entomological Society of Canada, 393 Winston Avenue, Ottawa, Ontario K2A 1Y8].

(5) Field, Bernard N. 1985. *Fields Virology*. Raven Press, New York.

(6) Godfrey, W.E. 1966. *The Birds of Canada*. National Museums of Canada, Bulletin No. 203. Ottawa, Ontario.

(7) Holt, John G. 1994. *Bergey's Manual of Determinative Bacteriology*. 9th edition. Williams & Wilkins, Baltimore, Md.

(8) Howard, R.J., J.A. Garland and W.L. Seaman. 1994. *Diseases and Pests of Vegetable Crops in Canada*. Entomological Society of Canada/ Canadian Phytopathological Society. Ottawa, Ontario.

(b) Precautions

The heading "PRECAUTIONS" must appear in capital letters. Information on any significant hazard relating to handling, storage, display, or distribution of the product must be outlined. Instructions on how to alleviate hazards, such as personal protective equipment (PPE), and where necessary, on decontamination must be stated.

Any significant hazard relating to human health, wildlife, or the environment that may result from use of the product must also be detailed on this panel, along with instructions on how to alleviate such hazards.

(c) Disposal

Product labels must carry appropriate disposal statements under the heading "DISPOSAL". The statements may vary depending on the classification and use of the products as well as the type of the containers.

Disposal label statements for commercial and restricted class products other than agriculture and non-crop land, where non-recyclable, non-returnable or non-refillable containers are used:

1. *Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.*
2. *Follow provincial instruction for any required additional cleaning of the container prior to its disposal.*
3. *Make the empty container unsuitable for further use.*
4. *Dispose of the container in accordance with provincial requirements.*
5. *For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.*

Commercial and Restricted class products used in agriculture and non-crop land where the products are marketed in recyclable, returnable or refillable containers:

For recyclable containers - The following statement would apply to plastic or metal containers that contain agricultural and non-crop land uses (e.g. forestry) pesticide products, and that are designed to contain 23L or less of product. These are "one-way" containers and are not reused.

Do not reuse this container for any purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

(1) Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.

(2) Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

For returnable containers - A container that is to be returned to the point of purchase by the user/grower. The container is collected from the point of purchase by the manufacturer, and returned to the manufacturing facility. At the manufacturing facility, the returnable container may either be refilled for future use, (e.g. next season) or disposed of by the manufacturer. The container is not refilled at the point of purchase. The following disposal statements are to be used:

Do not reuse this container for any purpose. For disposal, this empty container may be returned to the point of purchase (distributor/dealer).

For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

For refillable containers - The user/grower may return to the point of purchase with the empty container, and have it immediately refilled with the same product. The user/grower can also return the empty container to the point of purchase if he does not need more product. The container could then be refilled at the point of purchase, and the product sold to a second user/grower. The number of times the container is refilled at the point of purchase is dependent on the "life" of the container, which will vary from product to product. Once the "life" of the container has expired, it will be returned to the manufacturer. The following statements apply:

For disposal, this container may be returned to the point of purchase (distributor/dealer). It must be refilled by the distributor/dealer with the same product. Do not reuse this container for any other purpose.

For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

(d) First aid instructions

The heading, "FIRST AID" must appear in capital letters. Outline the practical measures to be taken in the event of poisoning, intoxication or injury caused by the product. The recommendations should describe measures that can be safely implemented prior to obtaining medical assistance. This section should not contain information directed towards medical professionals.

If medical attention is recommended under the FIRST AID section, the following statement should be added to the section: "Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention."

(e) Toxicological information

The heading "TOXICOLOGICAL INFORMATION" must appear in capital letters. Provide any information essential to the medical treatment of persons who have been poisoned, intoxicated or injured by the product. Include information on symptoms of poisoning or intoxication, antidote or remedial measures, and the identity of any ingredients in the product, such as petroleum distillates, that may affect the treatment. This information should be directed towards medical professionals and should not be mixed with the First Aid statement. This section is necessary for the following types of products, as a minimum:

- all products requiring the DANGER signal word as a result of systemic toxicity or eye and skin effects;
- any product that produces physiological effects requiring specific antidotal or medical treatment, such as cholinesterase inhibitor, metabolic stimulants, anticoagulants etc.; and
- all products that contain greater than or equal to 10% petroleum distillates.

(f) Notice to User

On COMMERCIAL, RESTRICTED and MANUFACTURING class labels the heading, "NOTICE TO USER" must appear in capital letters, followed by the exact statement:

> "This control product is to be used only in accordance with the directions on this label. It is an offense under the *Pest Control Products Act* to use a control product under unsafe conditions."

(g) Notice to Buyer

When a registrant wishes to include a limitation of warranty statement on the label of a control product, it must be exactly as follows, under the heading "NOTICE TO BUYER":

> "Seller's guarantee shall be limited to the terms set out on the label and, subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product and accepts the product on that condition."

7.3 Labelling Requirements for Dual-Purpose Products

Certain materials that are normally considered control products under the PCPA have uses that extend beyond the pest control function. Stain/wood preservatives represent examples of such dual-purpose products.

These products can be considered for labelling under provisions for non-primary control products. A product whose primary purpose is not for pest control, but is represented as having pest control properties, or that contains an active ingredient possessing such properties, can be labelled as follows:

7.3.1 Principal Display Panel

Product name, class designation, precautionary symbols, net contents, and name and address of registrant as detailed in 7.2, *General Labelling Requirements for Pest Control Products*.

7.3.2 Secondary Display Panel

(a) Guarantee statement and registration number as detailed in 7.2, *General Labelling Requirements for Pest Control Products*.

(b) First Aid as detailed in 7.2, *General Labelling Requirements for Pest Control Products*.

(c) Identification of any significant hazard(s) with respect to handling, storage, display, distribution, disposal, human health, wildlife, or the environment that may result from the use of the product shall be identified.

(d) Directions for use of the product.

7.4 Labelling for Products Sold in Water-Soluble Packaging

Control products that are sold in water-soluble packaging must bear the following labelling:

(a) **Overpack labelling** must contain all of the information required for primary control products. On the primary display panel of the overpack, instructions not to sell the soluble bags separately must be located in a conspicuous manner. Extra handling and storage precautions necessary for water-soluble bags must be included on the overpack on either the principal or secondary display panels.

(b) **Water-soluble bag labelling** must contain the following: identity of active ingredients, per cent concentration, type of formulation, type of product, net content statement, precautionary symbols, and "KEEP OUT OF REACH OF CHILDREN". This requirement may be waived if each soluble bag is individually overpacked, and the overpack is labelled as in 7.4(a) above.

7.5 Special Label Requirements for Restricted Uses

Where a control product has RESTRICTED uses on the label, the "NOTICE TO USER" statement must appear prominently at the top of the secondary display panel; followed by the "NATURE OF RESTRICTION" statement; followed by "RESTRICTED USES"; followed by the directions for use, rates of application, timing of applications and use limitations that apply. All of the above are enclosed in a dark heavy line, i.e., boxed in. Refer to Appendix H.

The "NATURE OF RESTRICTION" statement varies depending upon the use and is determined in consultation with the appropriate officers of the Agency. The following should serve as a guideline:

7.5.1 Storage/Display/Distribution Limitations

(a) Oral Toxicity ($LD_{50} \leq 50$ mg/kg bw): "This product is to be stored and displayed apart from food and feed."

This statement is routinely applied to labels of formulations having an oral LD_{50} of 50 mg/kg bw or less.

The nature of this restriction is directed to the conditions of storage and display reflecting the inherent toxicity of the compound, e.g., in case of accidental spills, and does not impose any additional limitations on the use of products so categorized.

(b) Inhalation or Percutaneous Toxicity (fumigants or dermal $LD_{50} \leq 100$ mg/kg): "This product is to be stored apart from lodging for humans, animal quarters, and normal work areas to avoid inadvertent exposure."

This statement is applied to: (1) gaseous or pressurized materials (fumigants) presenting a high inhalation toxicity hazard, e.g., aluminum phosphide, methyl bromide, chloropicrin, hydrogen cyanide; and (2) products having a dermal LD_{50} of 100 mg/kg bw or less.

7.5.2 Use Limitations

(a) Aquatic, Forest or Woodlands Uses: "This product is to be used only in the manner authorized; consult local pesticide regulatory authorities about use permits that may be required."

See also regulatory documents *Pesticides for Use in Forest and Woodlands Management*, and *Pesticides for Aquatic Applications*.

7.5.3 User Limitations

(a) Government Agencies and Pest Control Operators, e.g., 4-aminopyridine: "For use only by, or under the supervision of, government agencies and pest control operators; not for sale to the public."

(b) Government Agencies, e.g., 1080 for predator control in Alberta: "For sale only to persons authorized in government pest control programs."

(c) Signature Required, e.g., strychnine: "For use only by pest control operators, farmers, and persons authorized in government approved pest control programs where the vendor maintains a record of sales, including the name, address and signature of the purchaser, together with the quantity of product purchased."

This qualification is applied in situations where it may be desirable to identify and record the end user and/or to confine the sale of a highly toxic or persistent material to certain user groups.

(d) Veterinarian Use Only: "For use only by or under the supervision of licensed veterinarians."

7.6 Labelling for Small-Size Domestic Class Products

For products with very small labels, applicants may propose that some of the information normally required on the principal display panel be moved to the secondary display panel. This might include any of the following:

- guarantee;
- registration number;

- net contents; and
- name and postal address of registrant and agent.

This information should be located in the lower half of the secondary display panel. The product name, class designation, precautionary symbols, and direction to read the label must remain on the principal display panel.

7.7 Labelling of Shipping Cartons

Very often packages of pesticides are placed in larger cartons or bags for shipping. These shipping cartons or bags require a label containing the following information:

- product name;
- precautionary symbol;
- guarantee;
- registration number;
- gross net content;
- name and postal address of registrant; and
- instructions for handling broken cartons.

A copy of the registered label attached to the shipping carton is considered sufficient labelling. In addition, instructions for handling broken cartons should be provided if it is a concern.

7.8 Information to Accompany Bulk Shipments

Bulk shipment refers to a large quantity of a control product shipped by truck box, tank car or other means and which is not packaged as ordinarily understood, such as in boxes, cans or drums. A registered control product that is sold or distributed in bulk must have the following information on the bulk shipment and on, or attached to, the shipping bill:

- product name;
- class designation;
- guarantee statement;
- registration number;
- net contents;

- name and postal address of registrant and Canadian agent if the registrant is not located in Canada or the U.S.;
- toxicological information and first aid instructions;
- decontamination and disposal; and
- shipping/storage and handling information.

In current times, the availability of product in special bulk or mini bulk containers has become more common. If the product is shipped to the users in special bulk or mini bulk containers, the product must be accompanied by a complete product label. Therefore the following additional information must be shown:

- Precautionary Symbol;
- "READ THE LABEL BEFORE USING";
- Directions for Use; and
- Notice To User.

7.9 Printed Brochures and Leaflets

When the required labelling information is supplied in the form of a brochure or leaflet, the statement, "READ THE LABEL AND ATTACHED BROCHURE (OR LEAFLET) BEFORE USING", must appear prominently in capital letters on the label affixed to the container. When a technical bulletin is referred to as a part of the label, the statement should be: "READ THE LABEL AND ATTACHED TECHNICAL BULLETIN BEFORE USING".

In addition to whatever use directions may be included in the printed literature, the brochure, leaflet or technical bulletin must contain the product name, class designation, precautionary symbols, guarantee statement, registration number, name and postal address of the registrant, basic precautionary statements, and "READ THE LABEL BEFORE USING".

7.10 Supplemental Labels

Supplemental labels can be used to indicate newly accepted uses of a previously registered product until the next printing of the label. Both the supplemental label and the registered product label must accompany the product container at all times. The supplemental label must include the following:

- product name;
- class designation;
- precautionary symbols;

- "READ THE LABEL BEFORE USING";
- guarantee statement;
- registration number;
- name and postal address of registrant;
- basic precautionary statements;
- supplemental use directions; and
- special precautions, toxicological information and first aid instructions, as required.

7.11 Final Labels

Labelling is defined as the complete markings and text that appear on or accompany the product. Final labelling must be legible and the graphic design must not be misleading.

Procedures for submitting final labelling are as follows:

- When screen printing or embossing is used to print labelling directly on the container, e.g., cans, bottles, boxes, etc., do not submit the containers. Submit such labelling after it is reproduced as follows:
  (a) Screen printing: request that your printer supply finished copies of the labelling on paper for convenient filing.
  (b) Embossing: photocopy this labelling.
- When paste-on labelling is used, submit four (4) copies of the actual label (not photocopies).
- When labelling involves large containers, such as bags or boxes, submit legible photo-reduced copies, indicating the fraction of actual size.
- When labelling is small, attach the copies to sheets of paper before submitting.

Note: If labels are not being printed, e.g., for product not marketed in Canada, four (4) copies of the label text should be sent to the PMRA in order to complete the registration procedure. If at a later date the product is to be marketed in Canada, an application to amend the registration, including labels and applicable fee, must be made to the PMRA in advance.

To ensure that the printed labels are acceptable, the applicants are advised to read the following guide before submitting the final printed labels.

A Quality Assurance Guide for the Submission of Acceptable Printed Labels

To complete a registration, four printed labels (that which the consumer will see) must be submitted for each product. Printed labelling includes container labels as well as cartons, booklets, brochures and leaflets. To ensure that the printed label will be acceptable for the completion of product registration, remember to verify the following items:

Label Text and Layout

Always *proof read* the printed label by comparing it with the accepted draft label that has been initialled and dated by a PMRA official. The labels must match perfectly! Therefore when printing,

Do:

- ✔ Incorporate all corrections noted on the accepted draft label as well as those requested in the Letter of Acceptance that accompanies the accepted draft label.
- ✔ Ensure that changes noted for the text in one of the official languages, e.g., English, are also incorporated into the text of the other official language, e.g., French, where appropriate.
- ✔ Ensure that the print is legible, including size, colour and clarity.
- ✔ Road test the printed label by assuming the role of a consumer and answering the following questions:
  - Can the text be easily read?
  - Is the text large enough, and not obscured by the background text or colour of print?
  - Can the label be opened if peel-back/fold-out?
  - Has the printer provided the necessary label perforations?

Do Not:

- ✗ Add, delete or alter text, numbers, symbols or other graphics unless requested by PMRA officials.
- ✗ Reposition text in such a manner that violates the labelling requirements as set forth in the PCPR or Registration Handbook.
- ✗ Put a registrant's name and address on the label that differs from that on the application form.

Label Format

It is best to specify the proposed final label format at the draft stage. For example, if the product labelling includes both a container label and a booklet, submit both drafts for review. If the product labelling is of the crack and peel type so that the instructions may be removed, both the detachable portion and the portion that remains on the container must conform to labelling requirements. If a technical bulletin or product data sheet is to be included with the labelling, it should be submitted with the draft label.

Bilingual Labelling

In order to avoid rejection of bilingual printed labels due to incorrect translations, including rates of application, it is advisable to submit translated text in draft format for review prior to printing final labels.

Private Label Products

These labels must be identical to the initial product label except for trade dress, product name, company address and registration number. There must be no change in label format or text. Refer to the Regulatory document *Initial Product/Private Label Registration Process.*

Note: If you have any questions regarding requested changes to the draft label or other labelling concerns, contact a PMRA Registration Officer before printing the final label.

Examples of Common Printed Label Errors

The following are common errors that registrants make when printing final labels. These errors can easily be avoided by following the suggestions provided in this Registration Handbook.

- Errors in rates of applications. Watch the decimal points and zeroes!
- Omission of required text or symbols.
- Addition of pests or sites that were not on the accepted draft label.
- Addition of nonsensical text.
- Addition of unacceptable/unsupported graphics; and symbols, including drawings/pictures of pests or sites that are not listed on the label and environmental or Workplace Hazardous Materials Information System (WHMIS) symbols.
- Spelling errors that alter the meaning of text.
- Crack and peel labels that when unfolded have part of the label printed upside down, forcing the user to invert the product container in order to read the text.

- Poor translation, including the following: (a) text or rates of application in one language that do not match those in the other language; (b) omission of text in the translated version that was present in the original.
- Principal label panel text moved to the secondary label panel.
- Unacceptable print quality.
- Incorrect registration number.

7.12 Other Information on Label

(a) New or Improved Claims: Where the manufacturer changes the formulation or construction of a control product or device and wishes to claim that the product or formulation is "New" or "Improved", or a similar claim, the use of such wording will be limited to a two-year duration.

(b) Statements of Approval or Endorsement: It is not permissible on any label to indicate or imply in any manner that the PMRA endorses, recommends, or in any way encourages the use of the product.

(c) Additional written information relating to the control product, or other graphic designs or symbols may appear on the product label with the approval of the PMRA, provided this does not unreasonably detract from or obscure the mandatory information.

(d) Labelling requirements under the *Transportation of Dangerous Goods Act* (TDGA), should not be a part of the principal or secondary display panel. This additional information can be placed on the shipping boxes. When the information must be placed on the product container, it should be clearly separated from the pest control product label by means of graphic separations. In addition, the TDGA information should be identified as a requirement under the TDGA, e.g., by placing "*Transportation of Dangerous Goods Act* Classification" above the required TDGA symbol or wording.

7.13 WHMIS Labelling

WHMIS is a national information system intended to protect Canadian workers. It is legislated under the *Hazardous Products Act* (HPA). This system of information delivery has three key elements: labels, Material Safety Data Sheets (MSDSs), and worker education programs.

Pesticides were initially excluded from WHMIS requirements when the legislation was passed in 1987. In 1990, a tripartite Sectoral Committee comprised of pesticide manufacturers, labour and provincial occupational health and safety representatives reviewed the exclusion of pesticides and endorsed retaining the exemption from regulation under the HPA, but made several recommendations for implementation of some WHMIS requirements under the PCPA. In 1992, the Parliamentary Standing Committee on Consumer and Corporate Affairs and Government Operations accepted the recommendations of the Sectoral Committee but cautioned that when WHMIS requirements were to be implemented under the PCPA, the benefits obtained from WHIMS must outweigh the costs of the implementation.

In 1995, as per Treasury Board regulatory policy, a formal cost/benefit analysis was conducted by a private consultant on the committee recommendations related to labelling changes and MSDS provision for pesticides. The Agency will consider available options in light of the results of the analysis.

The PCPA and Regulations will require amendments to reflect the implementation decisions. Until procedures are finalized, the PMRA is not prepared to deal with label changes for WHMIS. However, registrants are encouraged to supply the Agency with MSDSs when available.

Part 8
Application for Registration of Products to be Used Only in Manufacturing of EPs and Classified As Manufacturing

8.1 Definitions

Products for manufacturing use only are classified as MANUFACTURING; these include TGAIs and MAs. They may also include ISPs when they are used for reformulating or repackaging. The definitions for these products and associated terms are provided in Appendix E, *Glossary of Terms Relating to a Product*.

8.2 Registration Requirements for Products Classified as MANUFACTURING

Registration requirements differ for the various types of MANUFACTURING products, e.g., TGAIs and MAs. Applications for registration should include the components specified below.

8.2.1 For TGAIs and ISPs:

- covering letter;
- *Application for New or Amended Registration* form;
- Product Chemistry: Complete set of information and materials as outlined in the Regulatory document *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*;
- four (4) hard copies and one electronic copy of the proposed draft label. See 8.3, *Labelling for Products Classified "Manufacturing"*;
- any other necessary supporting data*, indexed and supplied in adequate number of copies as per the Regulatory document *Organizing and Formatting a Complete Submission for Pest Control Products*; and

  ***Note:** Applications in support of registration of a TGAI or an ISP contained in products registered before January 1, 1984, should provide product chemistry data, and an index only to existing data.

- the completed *Fee Form* and the appropriate fee.

Note: Applications in support of registration of a new TGAI or an ISP, except for the IMEP, must be accompanied by an application to register an EP containing that active ingredient. See Section 9.2, *Registration Requirements,* for the data requirements for EPs.

8.2.2 For MAs:

- covering letter;
- *Application for New or Amended Registration* form;
- *Product Specification* form stating the source and registration number of each active ingredient and/or MA. For further chemistry information requirements, refer to the Regulatory document *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products*;
- LOC of source of supply for each active ingredient;
- any other necessary supporting data, indexed and supplied in adequate number of copies as per the Regulatory document *Organizing and Formatting a Complete Submission for Pest Control Products*;
- four (4) hard copies and one electronic copy of the proposed draft label. For more details, see 8.3, *Labelling for Products Classified "Manufacturing"*; and
- the completed *Fee Form* and the appropriate fee.

8.3 Labelling for Products Classified "Manufacturing"

Technical active ingredients, MAs and ISPs that are being imported into Canada or that are items of commerce in Canada require *printed* labels under the PCPA. If the product is not being imported into Canada, or is not an item of commerce in Canada, *typescript* labels will be accepted.

A sample label for a MP is provided in Appendix I. The approved label of the registered product must be on each unit package and also affixed to the outer package in which unit packages are distributed. For bulk shipments, e.g., tank cars, the label must be attached to the bill of lading or papers that accompany the shipment.

If a product is registered for both end-use and manufacturing use, only one registration number and label is required. The product label must meet the requirements specified in Sections 27 to 39 of the PCPR. Also see Part 7 of this document for more information on labelling.

Note: If a MP is registered for use with fertilizers only, the product label should have the following statement:

"To be used only in the manufacture of a fertilizer-pesticide that is registered under the *Fertilizers Act*."

The following statements should be used for most MPs, under the heading DISPOSAL:

> "Canadian formulators using this product should dispose of unwanted active ingredient and containers in accordance with municipal or provincial regulations. For additional details and information on clean up of spills, contact the provincial regulatory agency or the manufacturer."

Part 9
Application for Registration of End Use Products (EPs)

9.1 Definition

An EP is a product containing active ingredient(s) and usually formulant(s), that is labelled with instructions for direct pest control use or application.

9.2 Registration Requirements

Applications for registration of EPs should include the following:

- covering letter;
- *Application for New or Amended Registration* form;
- *Product Specification* form, stating the source and registration number of each registered active ingredient and MA, and the source and CAS number for each formulant;
- LOC for source of supply of TGAI or MA;
- four (4) hard copies and one electronic copy of the proposed draft label;
- chemistry data as per the Regulatory document *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products*, when required;
- any required supporting data properly indexed and organized as per the Regulatory document *Organizing and Formatting a Complete Submission for Pest Control Products,* supplied in sufficient copies as outlined in that document; and
- the completed *Fee Form* and the appropriate fee.

For more details about registration submissions, please see Part 5, *Applying For Registration - General Procedures.*

Part 10
Application for Registration of Special Groups of Pest Control Products

Most parts of this document apply to traditional pesticides - chemicals used for the control of insects, weeds, and plant diseases. Products described in this chapter differ from the traditional pesticides in their constituent materials or in their use patterns. In consideration of the special nature of these products, data requirements for registration differ somewhat from those for traditional pesticides. Part 10, *Application for Registration of Special Groups of Pest Control Products,* outlines the major differences.

10.1 Antimicrobial Pesticides

10.1.1 Definition

In 1972, products represented to control microorganisms became subject to regulation under the PCPA, with certain exceptions; see Part 3, *Exemptions*. For the purposes of the PCPA, an **antimicrobial pesticide** is defined as any product used for the control of bacteria, fungi, algae or viruses in or on inanimate objects and the environment, with the exception of food or feed.

Antimicrobial products include, but are not limited to, the product types listed below:

Antifouling paints: products that are coatings used to control aquatic fouling organisms, e.g., barnacles, mussels, molluscs, and algae, on ships, small boats, and other surfaces in freshwater and marine environments.

Bacteriostatic agents: products that inhibit bacterial growth and multiplication. Similarly, other static agents inhibit multiplication and growth of specific groups of microorganisms.

Hard surface disinfectants: products that destroy or inactivate microorganisms on inanimate surfaces.

Material preservatives: products that are usually applied during the manufacture of various materials to protect them against bacterial or fungal deterioration. Materials may include textiles, leather, aqueous emulsions, paints, packaging materials, plastics, vinyls, rubber, waxes, dyes, etc.

Oil field microbiocides: products that are used by the petroleum industry to control the growth of microorganisms in the drilling, extraction or refining processes.

Sanitizers: products that reduce the level of microorganisms present by significant numbers, i.e., 99.9% or more, or to acceptable levels established by federal or provincial health authorities.

Slimicides: products that are applied to industrial cooling or process waters to control the growth of slime-forming microorganisms.

Sporicides: products that destroy spores.

Swimming pool bactericides and algicides: products applied to water in pools, hot tubs, whirlpools and spas to control harmful bacteria and various species of algae.

Wood preservatives: products that when applied to wood prevent deterioration caused by various wood-destroying pests. The categories of products are largely defined by the use areas, e.g., lumber anti-sapstain; heavy duty or pressure treatment; joinery products; remedial, including ground line treatments; and stains.

Virucides: products that destroy viruses.

10.1.2 Products Also Subject to the FDA

In addition to the various classes of disinfectant products that are based on intended uses, a further division of each class can be made according to the area of use, such as the following:

(a) the home;

(b) industry (non-food processing);

(c) agriculture (non-food processing);

(d) hospitals; or

(e) food processing establishments.

10.1.2.1 Division of Disinfectant Products between the PMRA and the Therapeutic Products Directorate (TPD)

Health Canada outlined on January 28, 1997, the intent to consolidate responsibility for regulating hard surface disinfectants and sanitizers within the TPD, beginning April 1, 1997. Previously, disinfectant products with claims for use in hospitals and food-processing facilities were regulated by the TPD under the FDA, while products for use in industrial and agricultural situations, schools, and homes were regulated by the PMRA under the PCPA. The TPD will evaluate hard surface disinfectants and sanitizer uses associated with exempt disinfectants, i.e., disinfectant/sanitizer, issuing both a pest control product (PCP) registration number and a DIN as required until the amendment is finalized. For details, please refer to the PMRA Guidance Document, *Guideline for Determining Whether Disinfectant Products are Regulated by the Therapeutic Products Directorate or the Pest Management Regulatory Agency*.

10.1.2.2 Antimicrobial Products Other Than Disinfectants

Antimicrobial products other than those referenced in 10.1.2.1 may require a letter of no objection from the Food Packaging Materials and Incidental Additives, Chemical Health Hazard Assessment Division, Bureau of Chemical Safety, Food Directorate for particular uses to be added, e.g., a biocide used in the production of paper that will have contact with food.

10.2 Pheromones and Other Semiochemicals

Semiochemicals are message-bearing substances produced by plants or animals, or synthetic analogues of these substances, that evoke a behavioural response in individuals of the same or other species. Some examples of semiochemicals are allomones, kairomones, pheromones and synomones.

Pheromones are defined as a subgroup of semiochemicals that affect behaviour between members of the same species. In insects, these are predominantly mixtures of straight-chain unsaturated aliphatic alcohols, aldehydes and esters.

When used as pest control agents, pheromones and other semiochemicals are subject to regulation under the PCPA. Specific guidelines have been developed that recognize the unique characteristics of these substances - their low potential for exposure owing to low volumes of use, product packaging, use scenarios, and their generally species-specific and low-persistent nature. Please refer to the Regulatory document *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*.

10.3 Microbial Pest Control Agents

Microbial pest control involves the use of various naturally occurring or genetically modified microorganisms, including bacteria, algae, fungi, protozoa, viruses, mycoplasmae, rickettsiae and related organisms. Naturally occurring microorganisms are isolated from nature, selected by strain improvement, or developed by natural mechanisms, such as conjugation within the same species. Microorganisms can be indigenous, occurring naturally in ecozone(s) of intended use; or non-indigenous, occurring naturally in ecozone(s) different from those of the intended use. Genetically modified microorganisms are considered non-indigenous since they are not known to be naturally occurring.

Microbial agents represent very different groups of microorganisms, and specific guidelines have been developed that recognize their unique characteristics. For details, please refer to the Regulatory document *Guidelines for the Registration of Microbial Pest Control Agents and Products*. Applicants are encouraged to contact the PMRA for pre-submission consultation(s) during the development phase of the product. The main objectives of these consultations are to determine the appropriate test substances, study protocols and data that may be required for the registration of a particular proposed product as well as the type of information required to support data waivers. The guidelines indicated above also provide guidance for the preparation of a pre-submission consultation with the PMRA.

10.4 Devices

10.4.1 Definition

A device is defined as any article, instrument, apparatus, or contrivance that, by itself or in conjunction with a control product, is used as a means to control pests.

All devices listed in Schedule I of the PCPR are subject to regulation under the PCPA. These include the following:

(a) garment bags, cabinets or chests that are manufactured, represented or sold as a means of protecting clothing or fabrics from pests;

(b) devices used as a means of attracting and/or destroying flying insects;

(c) devices used as a means of repelling pests by causing physical discomfort through sound, touch or electromagnetic radiation;

(d) devices for attachment to garden watering hoses used as a means of dispensing or applying a control product;

(e) devices used as a means of providing automatic or unattended application of a control product; or

(f) devices that are sold for use with chemical products containing cyanide as a means of controlling animal pests.

Note: Devices that meet the applicable conditions described in Schedule II of the PCPR are subject to regulation but are exempt from registration. This includes devices used to attract and destroy flying insects by means other than the use of a chemical active ingredient. See Section 5(1)(c)(i) and Schedule II of the PCPR.

10.4.2 Registration Requirements

Application for registration of a pest control device should include the following:

- covering letter;
- *Application for New or Amended Registration* form;
- physical description and specifications;
- efficacy and safety data, when applicable;
- four (4) hard copies and one electronic copy of draft label, and associated promotional literature;
- CSA approval document and/or number; and

- the completed *Fee Form* and the appropriate fee.

10.4.3 Labelling Requirements for Devices

A device subject to regulation under the PCPA must bear a label in the following form:

(a) registration number, and name and postal address of registrant - as specified in 7.2, *General Labelling Requirements for Pest Control Products*; and

(b) identification of any significant hazard with respect to handling, storage, display, distribution, disposal, human health, wildlife, or the environment that may result from the use of the device.

Certain devices do not require registration under the PCPA and, therefore, do not require a registration number. Labelling requirements for these devices are referenced as items 8 and 9 of Schedule II of the PCPR, and include the following:

(a) a description of the device's function;

(b) the name and postal address of the Canadian agent or distributor; and

(c) identification of any significant hazard associated with the device and instructions for alleviating the hazard.

10.5 Plant Growth Regulators (PGRs)

PGRs are those substances used for controlling or modifying plant growth processes without severe phytotoxicity. PGRs are not conventional pesticides. They are, however, subject to regulation under the PCPA when they are used to control *any injurious or troublesome organic function of a plant.*

Currently, PGR products are regulated under either the PCPA or the *Fertilizers Act,* depending on the nature of their label claims as defined below:

10.5.1 Products regulated under the PCPA

Claims that a PGR functions to limit root development or the vegetative development of a plant are interpreted as pest control product claims and are subject to the PCPA. These claims also include modification of physiological, morphological and reproductive processes of plants other than those within the meaning of supplement. Such claims include, but are not limited to, the inhibition of sprouts or germination, fruit setting, sucker control, colour enhancement, defoliation and the control of pre-harvest drop.

Registration requirements for PGR products are similar to those for conventional pesticides.

10.5.2 Products regulated as supplements under the *Fertilizers Act*

Claims that a PGR functions to enhance root development or the vegetative development of a plant are interpreted as supplement claims and are subject to the *Fertilizers Act*. Such claims include, but are not limited to, breaking dormancy, induction of early germination or sprouting, root development and vegetative growth promotion. Supplement claims also include soil conditioning and any growth regulator property attributed to vitamins.

10.5.3 Products with both supplement claims and pest control products claims

Products containing only growth regulators, that carry mixed claims, are subject to registration under the PCPA contingent upon acceptance of the supplement claims under the *Fertilizers Act*. All other products with mixed claims will be subject to registration under the *Fertilizers Act*.

For further information regarding fertilizer claims of a PGR product, please contact the Fertilizer Section, Plant Products Division, Food Inspection Directorate, Canadian Food Inspection Agency, 59 Camelot Drive, Nepean, Ontario K1A 0Y9, tel.: (613) 952-8000.

10.6 Adjuvants

10.6.1 Adjuvants subject to registration

A pest control product includes any compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a pesticide to which it is added. Therefore, substances that are (a) components of end-use formulations, or (b) adjuvants that are sold and used separately for in-tank mixing by the end-user, are subject to regulation. The former are considered in the evaluation process for registration of the end-use formulation.

For adjuvants that are sold separately, the requirement for registration will depend on the intended use or label claim. Adjuvants of the activator or spray modifier type that are intended to directly improve efficacy or to enhance biological performance of the control product by modifying or enhancing physical or chemical characteristics will be subject to registration provisions of the PCPR. Utility modifier adjuvants that do not directly improve efficacy, but widen the conditions under which a control product is useful or maintain integrity of the spray diluent, will not be subject to registration. Examples of utility modifier adjuvants are buffering agents, antifoam agents, and pesticide/liquid fertilizer compatibility agents. However, such products with label claims for improved biological performance may require registration.

10.6.2 Labelling Requirements

In addition to the standard labelling requirements for format, precautionary symbols, etc., the label must indicate the following:

(a) the pesticide product(s) with which the adjuvant can be mixed;

(b) the type of formulation of those products;

(c) the crop, area, or animal on which the pesticide/adjuvant combination is to be applied; and

(d) any special equipment requirements or restrictions.

10.6.3 Information Requirements

Unlike the traditional pesticides, the technical active ingredient(s) present in an adjuvant product is (are) not required to be registered. The EP is registered solely on information available on the product.

For details, refer to the Regulatory document *Registration Requirements for Adjuvant Products*.

Part 11
Special Categories of Submissions

Part 11, *Special Categories of Submissions,* describes special categories of registration having requirements that deviate from regular registration procedures.

11.1 User Requested Minor Use Label Expansion (URMULE) - Category D

Minor uses of pesticides are defined as those uses for which the anticipated sales volume of a product is not sufficient to persuade the manufacturer to carry out the research required for registration. It is the projected sales of the pesticide product that is minor and not necessarily the plant or animal host or pest.

The Minor Use of Pesticides Program (MUPP) was established in the late 1970s. Following the recommendations of the PPR, the program has been renamed User-Requested Minor Use Label Expansion (URMULE). The program considers only the expansion of uses for products that are currently registered in Canada. The requirements for this program are as follows:

(a) the product must be registered in Canada,

(b) the registrant must be willing to add the new use to the label, and

(c) there must be grounds to expect that the pesticide will be effective for the proposed use.

The program is co-operative, involving the participation of sponsor groups, provincial coordinators, the PMRA, provincial government agencies and registrants. For details on the procedures, please refer to the Regulatory document *User-Requested Minor Use Label Expansion.*

URMULE Labelling

Certificates of Registration for URMULEs are granted based on submission and review of acceptable supplemental labels as described in 7.10, *Supplemental Labels.*

Since 1995, the following liability statement has been accepted for use on URMULE supplemental labels **when requested by the registrant.**

> NOTICE TO BUYER/USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR SPECIAL USE APPLICATIONS:
>
> The DIRECTIONS FOR USE for this product for the use(s) described on the Supplemental Label were developed by persons other than (COMPANY NAME) and accepted for registration by Health Canada under the User Requested Minor Use Label Expansion program. (COMPANY NAME) itself makes no representation or warranty with respect to performance (efficacy) and/or crop tolerance

> (phytotoxicity) claims for this product when used on the crop(s) listed on this Supplementary Label.
>
> Accordingly, the Buyer and User assume all liability arising, and agree to hold (COMPANY NAME) harmless from any claims based on efficacy and/or phytotoxicity in connection with the use(s) described on this Supplemental Label.

Registrants are requested to add accepted, registered URMULEs to their full product label at next printing. Only those uses accepted for registration with the liability statement on the supplemental label may use the liability statement on the final printed label. These URMULEs should be added to the full printed label and be enclosed within a box as illustrated below:

> Evening Primrose: Blight and dieback - Use 2.3 litres per hectare. Fall applications only. Apply to direct seeded fields after emergence when disease symptoms appear. Repeat once after 28 days or after 14 days if the conditions favour disease. Maximum of two applications per year.
>
> Ginseng: Leaf spot and grey mold - Use 2.4 - 4.8 litres per hectare. Start applications when disease threatens and repeat at 7-10 day intervals. DO NOT make more than six applications per season. DO NOT apply within 14 days of harvest.
>
> NOTICE TO BUYER/USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR SPECIAL USE APPLICATIONS:
> The DIRECTIONS FOR USE for this product for Evening Primrose and Ginseng were developed by persons other than ISK Biosciences Corporation and accepted for registration by the Pest Management Regulatory Agency under the User Requested Minor Use Label Expansion program. ISK Biosciences Corporation itself makes no representation or warranty with respect to performance (efficacy) and/or crop tolerance (phytotoxicity) claims for this product when used on Evening Primrose and Ginseng.
>
> Accordingly, the Buyer and User assume all liability arising, and agree to hold ISK Biosciences Corporation harmless from any claims based on efficacy and/or phytotoxicity in connection with the use described for Evening Primrose and Ginseng.

11.2 User Requested Minor Use Registration (URMUR) - Category A

This URMUR program is initiated based on the recommendations of the PRR. The program is designed to accomplish the following:

(a) permit sponsor/user groups to encourage registrants to apply for the registration of products that are registered in the U.S. or other OECD countries, for which they would not normally be prepared to apply, and to take on the responsibility for the generation of any required and supporting information;

(b) ensure that registration standards for URMUR applications are appropriate to the use, recognizing the relatively small sales volumes, use volumes and areas of use as well as the need to maintain Canadian standards of health and environmental protection; and

(c) ensure that the procedures for the technical review of URMUR applications are as efficient as possible by making use of foreign reviews completed by reliable regulators in other countries.

A complete submission consists of application forms, fee form and appropriate fee, supporting documents, and supporting data. For details on the procedures, please refer to the Regulatory document *User-Requested Minor Use Registration* (URMUR).

11.3 Temporary Registration - Category A or B

The PCPR provide for temporary registration of a product or use that does not fully meet regular registration requirements, for a period not exceeding one year, subject to associated terms and conditions. The registration is conditional on the applicant agreeing in writing to produce additional scientific or technical information related to the control product within a specified time period.

When the specified data requirements have been met, the applicant may apply to convert the temporary registration to a regular full registration. The applicant may also apply to extend a temporary registration, prior to its expiry, for another year. In either case, applications should include a covering letter, the application form, labels, and a fee form with the applicable fee.

11.4 Emergency Registration - Category B

This is a type of temporary registration for the purpose of controlling emergency pest infestations that are seriously detrimental to public health, domestic animals, natural resources or the environment. These registrations usually involve new uses of products that are already registered and have previously been subjected to a major review.

Applications for emergency registration must be submitted or supported by a federal agency or a provincial regulatory agency. A request is made in writing by the Deputy Minister or his/her official designee. When another user agency seeks an emergency registration, the application must either be submitted through the provincial regulatory agency or include a statement from that agency supporting the request. Details of the procedures and requirements are discussed in the Regulatory document *Registration of Pesticides for Emergency Use.*

11.5 Fast-Track Registration Streams - Category D

In order to improve operating efficiency and service to clients, a rapid, standardized review procedure for certain pest control product submissions has been implemented. The process involves review streams to which various submission types may be directed. Currently, two fast-track streams are operating: master copy product stream and private label product stream.

11.5.1 Master Copy Products

This stream fast-tracks the registration of master copy products. These are virtual copies, with only minor variants, of an already fully registered product, i.e., the master product. The master product registrant must first apply and be accepted for a master product registration status before master copy submissions can be considered. See 12.5, *Conversion to Master Product or Initial Product.*

The only allowable differences between a master copy and a master product are as follows:

(a) master copy products may be made on a different production line than the master product, i.e., in a different plant;

(b) master copy products may contain alternative sources of the same non-active ingredients;

(c) master copy product labels may contain all, or a subset of, the use claims found on the master product label; and

(d) master copy products may have a different product name, registrant and registration number.

Applications for registration of master copy products require the following:

- covering letter citing the master product registration number;
- *Application for New or Amended Registration* form;
- *Product Specification* form;
- LOC of source of supply from the manufacturer or supplier of each active ingredient. All active ingredients must be registered;
- four (4) hard copies and one electronic copy of the draft master copy label;
- letter of authorization from the master product registrant, acknowledging and approving the making of the application; and
- the completed *Fee Form* and the appropriate fee.

For further information, consult the Regulatory document *Master Product/Master Copy Registration Process.*

11.5.2 Private Label Products

This stream fast-tracks the registration process for private label (private brand) distributors. A private label product is a clone of an already fully registered product (the initial product), identical in every respect except for product name, registration number, company address, and label colour and type-set. The initial product registrant must first apply and be accepted for an initial product registration status before private label submissions can be accepted. See 12.5, *Conversion to Master Product or Initial Product.*

The initial product registrant handles private label registrations on behalf of the other companies. Registration renewal notices for private labels are sent only to initial product registrants.

Applications for registration of private label products require the following:

- covering letter, citing the initial product registration number;
- *Application for Registration of Private Label Product* form;
- four (4) printed labels for the private label product. It is the responsibility of the initial product registrant to assign consecutive registration numbers to private label applicants, e.g., the private labels for initial product XXXXX will have registration numbers XXXXX.01, XXXXX.02, etc.;
- a letter of authorization from the private label applicant if the initial product registrant is signing the application form on his/her behalf; and
- the completed *Fee Form* and the appropriate fee.

For further information, Please refer to the Regulatory document *Initial Product/ Private Label Registration Process.*

11.6 Importation for Manufacturing and Export Program (IMEP) - Category D

This program concerns the registration of pest control products (technical or formulated) imported solely for the purpose of manufacturing and export. The finished products are not to be used in Canada. Conditions and registration procedures and information requirements are outlined in the Regulatory document *Importation for Manufacturing and Export Program.*

In lieu of specified data, surrogate data or a request for waiver with a scientific rational will be considered. For chemical pesticides, it is necessary that the product imported into Canada be approved for sale or be registered in the U.S. or in a European Union or an OECD country. Also, pest control products for which registration has been previously suspended, cancelled or voluntarily withdrawn in Canada because of health and safety or environmental impact concerns, and pest control products that have been previously assessed for registration and found to be unacceptable are not eligible for the IMEP.

Application for registration under the IMEP should include the following:

- a covering letter briefly outlining the intent of the submission;
- a completed and signed *Application for New or Amended Registration* form;
- a completed and signed *Product Specification* form for the product to be imported;
- the completed *Fee Form* and the appropriate fee;

- three (3) copies of a draft, manufacturing-use label;
- a letter confirming the source of supply from the manufacturer of the technical active ingredient, if the applicant is not the manufacturer of the technical active ingredient under consideration; and
- three (3) copies of other information outlined in the Regulatory document *Importation for Manufacturing and Export Program*.

Products exported from Canada must be acceptable to the receiving country, and the Canadian exporter is responsible for obtaining the necessary approvals to allow the export of a finished product to the destination country.

Part 12
Amendment of Registration

After obtaining registration for a control product, registrants may, at times, wish to modify that registration in various ways. Also, registrants may be requested to amend their products or labelling to meet regulatory requirements currently in effect, e.g., upgrading precautionary statements. Amendments can involve changes to formulation, labelling, packaging, product status, or transfer of registration.

Each application to amend the registration of a product is assigned a submission number by the PMRA. A card attached to the back of the application form is returned to the registrant to inform him/her of this number. Please quote the submission number in all related correspondence or inquiries. Failure to do so could delay processing of the application.

When an application to amend a registration has been reviewed and found acceptable, the registrant is informed by letter of the decision and any conditions that may apply. If no label amendment is involved, a Certificate of Registration is issued.

If a label amendment is involved, a copy of the approved draft label is returned to the registrant, who may then print the label in accordance with the approved draft. Upon receipt of four (4) final, acceptable labels, the PMRA will issue the Certificate of Registration. Until this certificate has been issued, sale of the product under the amended condition is a violation of the PCPA.

An application to amend the registration of a control product must include the items listed below. The covering letter should provide a brief description of the registrant's request.

12.1 Amending Product Formulation

- covering letter;
- *Application for New or Amended Registration* form. Check *Amended* in appropriate box;
- *Product Specification* form;
- LOC of supply, if changing the source of active ingredient;
- supporting information - safety and efficacy data, if the composition of the formulation is changed significantly; and
- the completed *Fee Form* and the appropriate fee.

Note: Four copies of draft labels are required where the formulation change requires modification of the existing label.

12.2 Amending Product Label

- covering letter;

- *Application for New or Amended Registration* form. Check *Amended* in appropriate box;
- supporting information - safety and/or efficacy data, if new uses or methods of application are added;
- four (4) hard copies and one electronic copy of proposed draft label; and
- the completed *Fee Form* and the appropriate fee.

12.3 Amending Product Packaging

- covering letter;
- *Application for New or Amended Registration* form. Check *Amended* in appropriate box;
- *Product Specification* form. Specify the new packaging;
- four (4) hard copies and one electronic copy of the draft label if the new packaging involves a change of net contents and/or any changes to the label; and
- the completed *Fee Form* and the appropriate fee.

12.4 Amending Temporary Registration Status

The following requirements apply both to extension of temporary registration and conversion of a temporary registration to a full registration:

- covering letter;
- *Application for New or Amended Registration* form. Check *Reinstated* in box 8;
- requested information;
- four (4) hard copies and one electronic copy of previously accepted final label (not photocopies); and
- the completed *Fee Form* and the appropriate fee.

Note: An updated *Product Specification* form and a LOC of source of supply may be required for conversion from temporary to full registration.

12.5 Conversion to Master Product or Initial Product

Applications for changing from regular product status to an initial product or to a master product should include the following:

- covering letter;

- *Application for New or Amended* Registration form. Check *Amended* in appropriate box;
- *Product Specification* form;
- four (4) copies of the product label;
- LOC of source for each active ingredient - all active ingredients used in the product must be registered; and
- the completed *Fee Form* and the appropriate fee.

For further information on the registration of master products and initial products, consult the Regulatory documents *Master Product/Master Copy Registration Process*, and *Initial Product/Private Label Registration Process*, respectively.

12.6 Transfer of Registration

In order to document a change of ownership on the product register, the new owner must submit the following for each product to be transferred:

- covering letter;
- letter from the former registrant, confirming the sale or transfer of listed products and submissions and all supporting data to the new applicant;
- *Application for New or Amended Registration* form, indicating the new owner as applicant and signed by him/her;
- *Product Specification* form, indicating the new applicant;
- LOC of source of active ingredient(s); and
- four (4) hard copies and one electronic copy of the draft label, indicating the new company name and address;
- if the product being transferred is a technical active ingredient, an update of chemistry information for the active ingredient, as specified in the Regulatory document *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, parts 2.1-2.10 (inclusive); and
- the completed *Fee Form* and the appropriate fee.

12.7 Amendments Requiring a New Registration Number

There are certain limitations under which the registration of a product can be amended without changing the registration number. Any amendment that goes beyond that limitation will result in the requirement of a new registration number. The following are examples that will trigger the issuing of a new registration number:

(a) change in product guarantee as a result of formulation changes; and

(b) change in packaging of a product that results in wording changes throughout the label, e.g., water-soluble packaging, new sprayer system, etc.

Part 13
Renewal of Registration and Discontinuation of Sale or Distribution by the Registrant

13.1 Duration of Registration

In accordance with Section 14 of the PCPR, product registrations expire on December 31 of a designated year, not to exceed five years from December 31 of the year in which the product was registered, i.e., new registration, amendment, or renewal. In order to continue the registration status, the registration must be renewed.

13.2 Renewal of Registration

The registration of a product may be renewed by means of an *Application for Registration Renewal* form for additional periods not exceeding five (5) years each. All registrants having products due for registration renewal will receive a renewal notice. This notice includes one preprinted *Application for Registration Renewal* form, the *Fee Form* for each product subject to renewal, and other information concerning the renewal process. For more details, please refer to the Regulatory document *Renewal of Registration of Pest Control Products*.

Registration renewal does not involve a review of data or a call for data. It entails an obligation for registrants to confirm that certain information contained in the product register is current, correct, and consistent with the product being marketed under that registration number. Renewal also provides an opportunity to review product registers for notification and non-notification violations.

To allow sufficient time for processing, registrants should apply for renewal as soon as possible after receiving the renewal notice. Submissions for renewal should include the following:

- *Application for Registration Renewal* form: This form lists the product subject to renewal. The registrant should verify all information on the form and indicate the status of the product. The form should be signed and dated by the registrant or an authorized officer. Registrants of initial products are responsible for renewing all associated private label products.

- Labels: Attach four (4) sets of the printed labels for each product to be renewed.

- The completed *Fee Form* and the appropriate fee.

Note: It is not possible under the registration renewal process to consider amendments to product labels or to extend the registration of temporary products or uses. Any such requests for changes must be submitted by means of an *Application for New or Amended Registration* form, separately from registration renewal. See Sections 12.2, *Amending Product Label*, and 12.4, *Amending Temporary Registration Status*, respectively, for amending product label and amending temporary registration.

13.3 Discontinuation of Sale or Distribution by the Registrant

Under Section 16 of the PCPR, a registrant who intends to discontinue sale or distribution of a product must inform the Minister of that intention.

While an application to discontinue the sale or distribution of a product by the registrant is usually done at the time of registration renewal, the registrant may make such a request at any time during the registration period. The granting of such a request is up to the discretion of the Minister and is subject to such terms and conditions as the Minister may specify.

For details of the processes for discontinuation and application for reinstatement of discontinued products (or registration not renewed), please refer to the Regulatory document *Renewal of Registration of Pest Control Products*.

Part 14
Cancellation and Suspension of Registration

At any time during the registration period, the registration of a product may be suspended or cancelled if the product is found to present an unacceptable risk of harm to human health or the environment, or if it no longer meets the criteria of *merit or value* for its intended uses. The consequences of these actions are outlined in the following sections.

14.1 Cancellation of Registration

Cancellation of registration is the most severe regulatory action imposed on a product. This action immediately stops the production, sale and use of the product. Cancellation of registration may be appealed by the registrant, in writing to the Minister, within 30 days of the day on which the notice of regulatory action was received.

14.2 Suspension of Registration

Suspension of registration immediately stops further distribution of the suspended product by the registrant. Stock remaining on the retail market prior to the suspension action may be legally sold and used subject to any terms and conditions that have been specified by the Minister. Suspension of registration may be appealed by the registrant, in writing to the Minister, within 30 days of the day on which the notice of regulatory action was received.

Part 15
Re-evaluation and Special Review

15.1 Re-evaluation

The purpose of re-evaluation is to accomplish the following:

(a) identify and fill data gaps, thus bringing older data bases up to modern standards;

(b) identify and examine concerns regarding human safety or adverse environmental effects;

(c) ensure continued efficacy; and

(d) take appropriate regulatory steps to remove those products that are no longer effective or that pose an unacceptable risk of harm to people or the environment.

In response to the stakeholder recommendations outlined in the 1990 PRR to establish re-evaluation and special review processes, the Government committed to enhancing the existing program. As a result of this commitment, re-evaluation is indeed a priority for the Agency. In order to balance the Government commitments to improve performance standards and to enhance the re-evaluation program, the Agency will phase in the re-evaluation program as efficiency gains and enhanced harmonization are achieved.

15.2 Special Review

Special Review refers to the examination of certain data pertaining to a control product in response to specific concerns about the product, e.g., potential carcinogenicity, teratogenicity, bio-accumulation, and applicator exposure. The purpose is to examine the specific concern in light of current knowledge and to mitigate the concern through appropriate regulatory steps.

A special review of a pesticide may be initiated when specific concerns have been identified with the pesticide, based on new evidence and/or regulatory actions taken by other countries. The registrant(s) of the pesticide will be notified of the special review and asked to submit all available information pertaining to the specific concerns. Additional studies may be requested from the registrant(s) if necessary. A regulatory decision will be made based on a review of the data and a risk/benefit assessment.

15.3 Regulatory Changes

Re-evaluation or special reviews may lead to regulatory changes that range from minor deletions from product labels or redefined conditions for use, to suspension or cancellation of registered products.

Part 16
Importation of Pest Control Products

16.1 General Procedures

Control products imported into Canada must be accompanied by the *Declaration by Importer of Control Products* form, signed by the importer of the material. Forms are available from Canadian Customs entry points or from the PMRA or the Regional Offices of the PMRA. See Appendix B, *PMRA Regional Offices*.

Resale

Products for resale must be registered in Canada under the PCPA before the importation is permitted.

Manufacturing

Materials imported for manufacturing use must either be registered themselves, or the EP(s) based on these materials must be registered. Products imported solely for manufacturing and export are subject to the PCPR; requirements are outlined in the Regulatory document *Importation for Manufacturing and Export Program*.

Research

Materials imported for research purposes may not require registration, but must meet the requirements set forth in the PCPR. Please note that a research permit may be necessary to conduct research in Canada. For more information, see Part 4, *Research Permits*, of the Registration Handbook.

Personal Use

Products imported for personal use must meet the requirements specified in Section (4) of the PCPR. A product can be imported into Canada for personal use if the total quantity of the control product does not exceed 500 grams by mass and 500 millilitres by volume, and it does not have a monetary value exceeding $10.00 Canadian.

Products for importation that do not have the accompanied form or necessary documentation and that do not meet the requirements set forth in this section will be detained at the border, pending further investigation.

16.2 Pesticide Own-Use Import Program (OUI)

This program allows users to import designated pesticides for their own use. It helps to ensure that Canadian agricultural producers have access to competitively priced pesticides. Under the program, only products equivalent to those registered in Canada can be imported.

The program is a two-step process. In the first step, individuals or a user/commodity group apply to have a foreign product accepted into the program. In the second step, the individuals or group apply for a permit, using the *Pesticide Own-Use Import Form,* to import the product into Canada and then bring it through customs. For details, refer to the OUI information kit, which is available from the PMRA or its Regional Offices. See Appendix B, *PMRA Regional Offices*.

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List of Documents Referenced in the Registration Handbook

- *Assessment of the Economic Benefits of Pesticides* - Regulatory Directive Dir93-17
- *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products* - Regulatory Directive Dir98-03
- *Chemical Pesticide Research Permit Guidelines* - Regulatory Directive Dir98-05
- *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product* - Regulatory Directive Dir98-04
- *Comprehensive Data Summaries* - Regulatory Directive Dir96-05 and Dir97-01
- *Good Laboratory Practices* - Regulatory Directive Dir98-01
- *Guidance Document on Pest Control Product Cost Recovery Fees* (1997)
- *Guidelines for Determining Environmental Chemistry and Fate of Pesticides* - Trade Memorandum T-1-255
- *Guideline for Determining Whether Disinfectant Products are Regulated by the Therapeutic Products Directorate or the Pest Management Regulatory Agency* (1997)
- *Guidelines for Developing a Pesticide Toxicology Data Base* - Trade Memorandum T-1-245
- *Guidelines for Efficacy Assessment of Chemical Pesticides* - Regulatory Directive Dir93-07a
- *Guidelines for Efficacy Assessment of Fungicides, Bactericides and Nematicides* - Regulatory Directive Dir96-01
- *Guidelines for Efficacy Assessment of Herbicides and Plant Growth Regulators* - Regulatory Directive Dir93-07b
- *Guidelines for the Registration of Microbial Pest Control Agents and Products* - Regulatory Proposal Pro98-01
- *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals* - Regulatory Directive Dir97-02
- *Importation for Manufacturing and Export Program* - Regulatory Directive Dir95-05

- *Initial Product/Private Label Registration Process* - Regulatory Directive Dir93-21
- *Management of Submissions Policy* - Regulatory Proposal Pro96-01
- *Master Product/Master Copy Registration Process* - Regulatory Directive Dir93-20
- *Organizing and Formatting a Complete Submission for Pest Control Products* - Regulatory Proposal Pro98-02
- *Pesticides for Aquatic Applications* - Regulatory Directive Dir93-12
- *Pesticides for Use in Forest and Woodlands Management* - Regulatory Directive Dir93-10
- *Registration of Pesticides for Emergency Use* - Regulatory Directive Dir94-05
- *Registration Requirements for Adjuvant Products* - Regulatory Directive Dir93-15
- *Renewal of Registration of Pest Control Products* - Regulatory Directive Dir98-06
- *Research Permit Guidelines for Microbial Pest Control Agents* - Regulatory Proposal Pro93-05
- *Residue Chemistry Guidelines* - Regulatory Directive Dir98-02
- *User-Requested Minor Use Registration (URMUR)* - Regulatory Proposal Pro97-04
- *User-Requested Minor Use Label Expansion* - Regulatory Directive Dir93-23

Note: These documents are subject to revision. A revised document will be reissued under a new number and the title may be slightly modified. This Appendix will be updated as required to reflect the current versions of PMRA guidance documents.

Appendix B

PMRA Regional Offices

Atlantic
Pest Management Regulatory Agency
Regional Manager
1081 Main Street
P.O. Box 6088
Moncton, New Brunswick
E1C 8R2
Tel: 506-851-7671
FAX: 506-851-2689
MCTIERNANN@EM.AGR.CA

Quebec
Pest Management Regulatory Agency
Regional Manager
2001 University
7th floor
Montréal, Quebec
H3A 3N2
TEL:514-283-8888
FAX: 514-283-1919
LAFORTUNEJ@EM.AGR.CA

Ontario
Pest Management Regulatory Agency
Regional Manager
174 Stone Road, West
Guelph, Ontario
N1Q 4S9
TEL: 519-837-9400
FAX:519-837-9773
PETTIGREWR@EM.AGR.CA

Manitoba
Pest Management Regulatory Agency
Regional Manager
613-269 Main Street
Winnipeg, Manitoba
R3C 1B2
TEL:204-983-8662
FAX:204-983-8022
SVANWALLEGHE@EM.AGR.CA

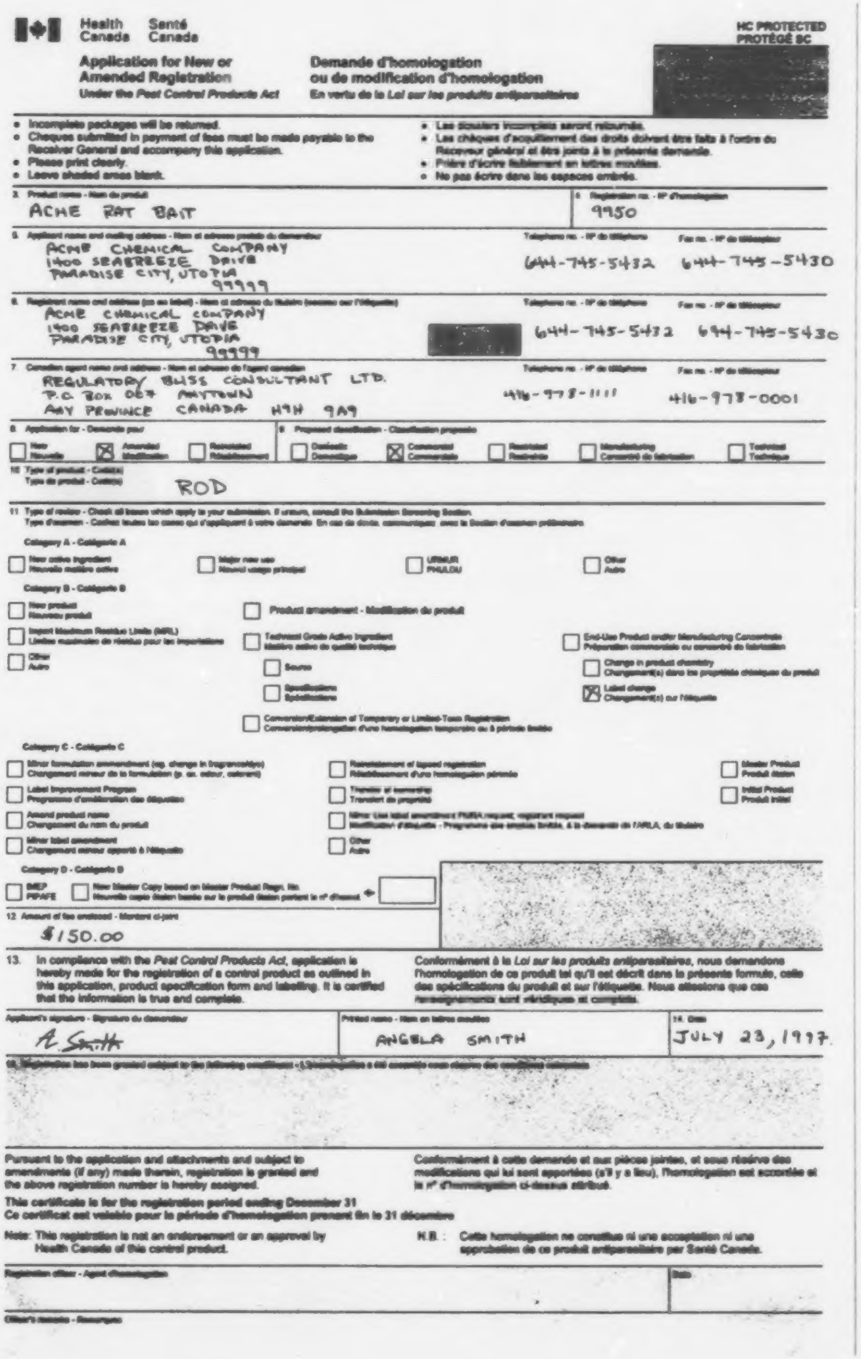
Saskatchewan
Pest Management Regulatory Agency
Regional Manager
Room 300 Walter Scott Bldg.
3085 Albert Street
P.O. Box 8060
Regina, Saskatchewan
S4P 4E3
TEL: 306-780-7123
FAX: 306-780-5177
BMAKSYMETZ@EM.AGR.CA

Alberta
Pest Management Regulatory Agency
Regional Manager
Room 654, Harry Hays Bldg.
200 4th Ave. S.E.
Calgary, Alberta
T2G 4X3
TEL:403-292-4106
FAX:403-292-6629
GORDONBD@EM.AGR.CA

British Columbia
Pest Management Regulatory Agency
Regional Manager
Room 202, 620 Royal Avenue
P.O. Box 2523
New Westminster, British Columbia
V3L 5A8
TEL: 604-666-0741
FAX: 604-666-6130
RUPNERSI@EM.AGR.CA

Appendix C

Application for New or Amended Registration Form - Example



Health Canada Santé Canada

HC PROTECTED
PROTÉGÉ SC

Application for New or Amended Registration
Under the Pest Control Products Act

Demande d'homologation ou de modification d'homologation
En vertu de la Loi sur les produits antiparasitaires

- Incomplete packages will be returned.
- Cheques submitted in payment of fees must be made payable to the Receiver General and accompany this application.
- Please print clearly.
- Leave shaded areas blank.

- Les dossiers incomplets seront retournés.
- Les chèques d'acquittement des droits doivent être faits à l'ordre du Receveur général et être joints à la présente demande.
- Prière d'écrire lisiblement en lettres moulées.
- Ne pas écrire dans les espaces ombrés.

3. Product name - Nom du produit: ACHE RAT BAIT

4. Registration no. - N° d'homologation: 9950

5. Applicant name and mailing address - Nom et adresse postale du demandeur:
ACME CHEMICAL COMPANY
1400 SEABREEZE DRIVE
PARADISE CITY, UTOPIA
99999
Telephone no. - N° de téléphone: 644-745-5432
Fax no. - N° de télécopieur: 644-745-5430

6. Registrant name and address (as on label) - Nom et adresse du titulaire (comme sur l'étiquette):
ACME CHEMICAL COMPANY
1400 SEABREEZE DRIVE
PARADISE CITY, UTOPIA
99999
Telephone no. - N° de téléphone: 644-745-5432
Fax no. - N° de télécopieur: 644-745-5430

7. Canadian agent name and address - Nom et adresse de l'agent canadien:
REGULATORY BLISS CONSULTANT LTD.
P.O. BOX 007 ANYTOWN
ANY PROVINCE CANADA H9H 9A9
Telephone no. - N° de téléphone: 416-978-1111
Fax no. - N° de télécopieur: 416-978-0001

8. Application for - Demande pour
☐ New / Nouvelle ☒ Amended / Modification ☐ Reinstated / Rétablissement

9. Proposed classification - Classification proposée
☐ Domestic / Domestique ☒ Commercial / Commerciale ☐ Restricted / Restreinte ☐ Manufacturing / Concentré de fabrication ☐ Technical / Technique

10. Type of product - Code(s) / Type de produit - Code(s): ROD

11. Type of review - Check all boxes which apply to your submission. If unsure, consult the Submission Screening Section.
Type d'examen - Cochez toutes les cases qui s'appliquent à votre demande. En cas de doute, communiquez avec la Section d'examen préliminaire.

Category A - Catégorie A
☐ New active ingredient / Nouvelle matière active
☐ Major new use / Nouvel usage principal
☐ URMUR / PHULDU
☐ Other / Autre

Category B - Catégorie B
☐ New product / Nouveau produit
☐ Import Maximum Residue Limits (MRL) / Limites maximales de résidus pour les importations
☐ Other / Autre
☐ Product amendment - Modification du produit
☐ Technical Grade Active Ingredient / Matière active de qualité technique
☐ Source
☐ Specifications / Spécifications
☐ End-Use Product and/or Manufacturing Concentrate / Préparation commerciale ou concentré de fabrication
☐ Change in product chemistry / Changement(s) dans les propriétés chimiques du produit
☒ Label change / Changement(s) sur l'étiquette
☐ Conversion/Extension of Temporary or Limited-Term Registration / Conversion/prolongation d'une homologation temporaire ou à période limitée

Category C - Catégorie C
☐ Minor formulation amendment (eg. change in fragrance/dye) / Changement mineur de la formulation (p. ex. odeur, colorant)
☐ Label Improvement Program / Programme d'amélioration des étiquettes
☐ Amend product name / Changement du nom du produit
☐ Minor label amendment / Changement mineur apporté à l'étiquette
☐ Reinstatement of lapsed registration / Rétablissement d'une homologation périmée
☐ Transfer of ownership / Transfert de propriété
☐ Minor Use label amendment PMRA request, registrant request / Modification d'étiquette - Programme des emplois limités, à la demande de l'ARLA, du titulaire
☐ Other / Autre
☐ Master Product / Produit étalon
☐ Initial Product / Produit initial

Category D - Catégorie D
☐ SMEP / PIPAFE
☐ New Master Copy based on Master Product Regn. No. / Nouvelle copie étalon basée sur le produit étalon portant le n° d'homol. → ☐

12. Amount of fee enclosed - Montant ci-joint: $150.00

13. In compliance with the *Pest Control Products Act*, application is hereby made for the registration of a control product as outlined in this application, product specification form and labelling. It is certified that the information is true and complete.

Conformément à la *Loi sur les produits antiparasitaires*, nous demandons l'homologation de ce produit tel qu'il est décrit dans la présente formule, celle des spécifications du produit et sur l'étiquette. Nous attestons que ces renseignements sont véridiques et complets.

Applicant's signature - Signature du demandeur: A. Smith
Printed name - Nom en lettres moulées: ANGELA SMITH
14. Date: JULY 23, 1997.

15. Registration has been granted subject to the following conditions - L'homologation a été accordée sous réserve des conditions suivantes

Pursuant to the application and attachments and subject to amendments (if any) made therein, registration is granted and the above registration number is hereby assigned.

Conformément à cette demande et aux pièces jointes, et sous réserve des modifications qui lui sont apportées (s'il y a lieu), l'homologation est accordée et le n° d'homologation ci-dessus attribué.

This certificate is for the registration period ending December 31
Ce certificat est valable pour la période d'homologation prenant fin le 31 décembre

Note: This registration is not an endorsement or an approval by Health Canada of this control product.

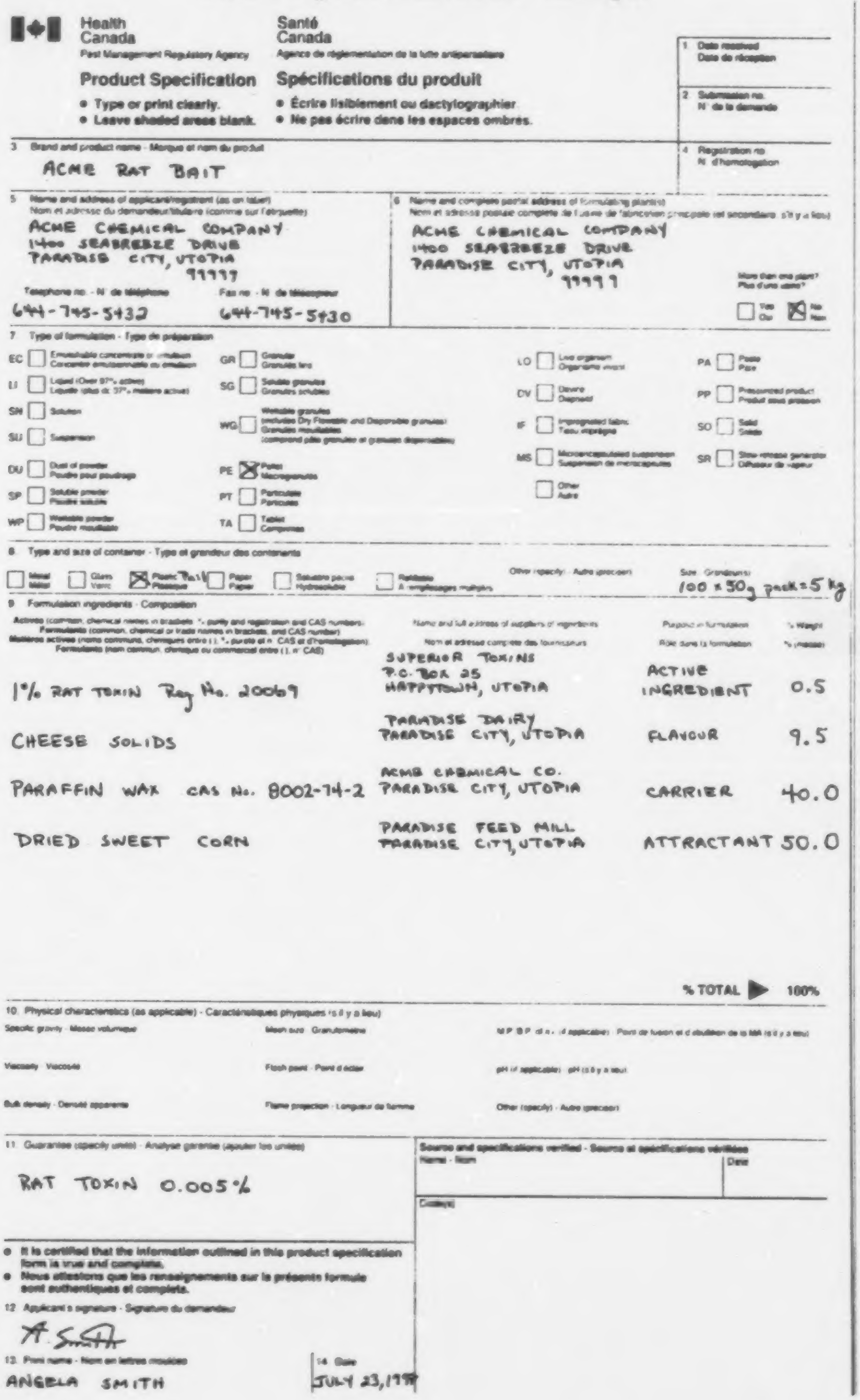
N.B. : Cette homologation ne constitue ni une acceptation ni une approbation de ce produit antiparasitaire par Santé Canada.

Registration officer - Agent d'homologation
Date

Officer's initials - Paraphe

Appendix D

Product Specification Form - Example



Health Canada / Santé Canada
Pest Management Regulatory Agency / Agence de réglementation de la lutte antiparasitaire

Product Specification / **Spécifications du produit**

- Type or print clearly. / Écrire lisiblement ou dactylographier.
- Leave shaded areas blank. / Ne pas écrire dans les espaces ombrés.

1 Date received - Date de réception
2 Submission no. - N° de la demande
3 Brand and product name - Marque et nom du produit: ACME RAT BAIT
4 Registration no. - N° d'homologation

5 Name and address of applicant/registrant (as on label) - Nom et adresse du demandeur/titulaire (comme sur l'étiquette)

ACME CHEMICAL COMPANY
1400 SEABREEZE DRIVE
PARADISE CITY, UTOPIA
99999

Telephone no. - N° de téléphone: 644-745-5432
Fax no. - N° de télécopieur: 644-745-5430

6 Name and complete postal address of formulating plant(s) - Nom et adresse postale complète de l'usine de formulation principale (et secondaire, s'il y a lieu)

ACME CHEMICAL COMPANY
1400 SEABREEZE DRIVE
PARADISE CITY, UTOPIA
99999

More than one plant? - Plus d'une usine? ☐ Yes/Oui ☒ No/Non

7 Type of formulation - Type de préparation

EC ☐ Emulsifiable concentrate or emulsion / Concentré émulsionnable ou émulsion
LI ☐ Liquid (Over 97% active) / Liquide (plus de 97% matière active)
SN ☐ Solution
SU ☐ Suspension
DU ☐ Dust or powder / Poudre pour poudrage
SP ☐ Soluble powder / Poudre soluble
WP ☐ Wettable powder / Poudre mouillable
GR ☐ Granular / Granulés fins
SG ☐ Soluble granules / Granulés solubles
WG ☐ Wettable granules (includes Dry Flowable and Dispersible granules) / Granulés mouillables (comprend pâte granulée et granulés dispersables)
PE ☒ Pellet / Microgranulés
PT ☐ Particulate / Particules
TA ☐ Tablet / Comprimés
LO ☐ Live organism / Organisme vivant
DV ☐ Device / Dispositif
IF ☐ Impregnated fabric / Tissu imprégné
MS ☐ Microencapsulated suspension / Suspension de microcapsules
☐ Other / Autre
PA ☐ Paste / Pâte
PP ☐ Pressurized product / Produit sous pression
SO ☐ Solid / Solide
SR ☐ Slow-release generator / Diffuseur de vapeur

8 Type and size of container - Type et grandeur des contenants

☐ Metal / Métal ☐ Glass / Verre ☒ Plastic Pail / Plastique ☐ Paper / Papier ☐ Soluble pack / Hydrosoluble ☐ Refillable / À remplissages multiples
Other (specify) - Autre (préciser)
Size - Grandeur(s): 100 × 50g pack = 5 kg

9 Formulation ingredients - Composition

Actives (common, chemical names in brackets, % purity and registration and CAS numbers) Formulants (common, chemical or trade names in brackets, and CAS number) / Matières actives (noms communs, chimiques entre ( ), % pureté et n° CAS et d'homologation) Formulants (nom commun, chimique ou commercial entre ( ), n° CAS)	Name and full address of suppliers of ingredients / Nom et adresse complète des fournisseurs	Purpose in formulation / Rôle dans la formulation	% Weight / % (masse)
1% RAT TOXIN Reg. No. 20069	SUPERIOR TOXINS P.O. BOX 25 HAPPYTOWN, UTOPIA	ACTIVE INGREDIENT	0.5
CHEESE SOLIDS	PARADISE DAIRY PARADISE CITY, UTOPIA	FLAVOUR	9.5
PARAFFIN WAX CAS No. 8002-74-2	ACME CHEMICAL CO. PARADISE CITY, UTOPIA	CARRIER	40.0
DRIED SWEET CORN	PARADISE FEED MILL PARADISE CITY, UTOPIA	ATTRACTANT	50.0

% TOTAL ▶ 100%

10 Physical characteristics (as applicable) - Caractéristiques physiques (s'il y a lieu)

Specific gravity - Masse volumique
Mesh size - Granulométrie
M.P./B.P. of a.i. (if applicable) - Point de fusion et d'ébullition de la MA (s'il y a lieu)
Viscosity - Viscosité
Flash point - Point d'éclair
pH (if applicable) - pH (s'il y a lieu)
Bulk density - Densité apparente
Flame projection - Longueur de flamme
Other (specify) - Autre (préciser)

11 Guarantee (specify units) - Analyse garantie (ajouter les unités): RAT TOXIN 0.005%

Source and specifications verified - Source et spécifications vérifiées
Name - Nom
Date
Code(s)

- It is certified that the information outlined in this product specification form is true and complete.
- Nous attestons que les renseignements sur la présente formule sont authentiques et complets.

12 Applicant's signature - Signature du demandeur: A. Smith

13 Print name - Nom en lettres moulées: ANGELA SMITH

14 Date: JULY 23,1998

]

Appendix E

Glossary of Terms Relating to a Product

Active Ingredient (AI): The ingredient(s) of a control product to which the effects of the pest control product are attributed, including a synergist, but does not include a solvent, diluent, emulsifier or component that by itself is not primarily responsible for the effect of the product.

End-Use Product (EP): A product containing active ingredient(s) and usually formulant(s) that is labelled with instructions for direct pest control use or application.

Formulant or **Non-Active Ingredient**: Any substance or group of substances other than an active ingredient that is intentionally added to a pest control product to improve its physical characteristics, e.g., sprayability, solubility, spreadability, and stability.

Impurity: Any substance in a control product other than an active ingredient or a formulant, e.g., contaminants, residual starting materials, reaction products, degradation products or products added for purposes of extraction or purification.

Integrated System Product (ISP): May be used in manufacture of an EP or may itself be an EP; formed in a manufacturing process in which the ISP (a) contains an active ingredient that is not isolated due to physical limitations or uncertainty as to the specific active component(s); or (b) is purposely left as a mixture of components due to manufacturing or integrity considerations.

Manufacturing Concentrate (MA): A product containing a registered technical active ingredient(s) and formulant(s) intended for further reformulating and/or repackaging into EPs.

Manufacturing-use Product (MP): Products for manufacturing use only that include TGAIs and MAs. It may also include ISPs when they are used for reformulating or repackaging.

Technical Active Ingredient or **Technical Grade of Active Ingredient (TGAI)**: The TGAI contains the active ingredient and normally contains impurities that are by-products of the manufacturing process.

Appendix F

SAMPLE LABEL FORMAT FOR DOMESTIC PRODUCT

ENGLISH VERSION

PRINCIPAL PANEL

D-BUG

Ready-To-Spray Insecticide
for Lawns

To control: ants, chinch bugs, white grubs

DOMESTIC

READ THE LABEL BEFORE USING

KEEP OUT OF REACH OF CHILDREN

GUARANTEE: (Chemical Name of Active Ingredient) x%

REG. NO. XXXXX P.C.P. ACT

Precautionary Symbols and Signal Words (as required)

Net Contents: 1 L

Your Company
Your Postal Address
Your City, Your Province
Postal Code

SECONDARY PANEL

DIRECTIONS: Attach hose, open system, turn "on" and spray.

This container covers the following areas:

Ants: 170-340 sq. metres (1800-3700 sq. ft). Wet grass thoroughly before treatment.

Chinch bugs: 275 sq. metres (3000 sq. ft). Wet grass thoroughly before treatment. Repeat in 7-10 days if necessary.

White grubs: 200 sq. metres (2200 sq. ft). Water grass thoroughly after application or apply during rain. Apply between late July and early October.

KEEP CHILDREN AND PETS OFF TREATED AREA FOR 24 HOURS OR UNTIL DRY.

PRECAUTIONS: KEEP OUT OF REACH OF REACH OF CHILDREN AND PETS. Do not allow others, such as children and pets, on treatment area during application or to re-enter treated areas until spray has dried. Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin, clothing and inhalation of spray mist. Wear rubber gloves when handling and measuring. Wash hands thoroughly after handling and before eating, drinking, etc. Do not contaminate food, food utensils, feed or water. Do not use in home. Do not store or use near heat or flame. Toxic to bees, birds, fish and wildlife, including waterfowl.

FIRST AID: If swallowed, do not induce vomiting. Obtain medical attention or call a poison control centre immediately. If on skin, remove contaminated clothing and wash thoroughly with soap and water. If in eyes, flush with water for 10 minutes and obtain medical attention. Take container, label or product name and PCP Registration Number with you when seeking medical attention.

TOXICOLOGICAL INFORMATION: (as appropriate)

DISPOSAL: Do not re-use empty container. Wrap and dispose of empty container with household garbage.

SAMPLE LABEL FORMAT FOR DOMESTIC PRODUCT

FRENCH VERSION

PRINCIPAL PANEL

D-BUG

Insecticide prêt-à-pulvériser pour pelouses

Combat les fourmis, les punaises des céréales, les vers blancs

DOMESTIQUE

LIRE L'ÉTIQUETTE AVANT L'EMPLOI

GARDER HORS DE LA PORTÉE DES ENFANTS

GARANTIE : (nom chimique de la matière active) x %

NO. D'HOMOL. XXXXXX LOI P.A.

Contenu net : 1 L

Symboles avertisseurs et mises en garde (selon le produit)

nom de la compagnie
numéro et nom de la rue
ville (province)
code postal

SECONDARY PANEL

MODE D'EMPLOI : Fixer le tuyau d'arrosage, ouvrir le système, mettre à "ON" et pulvériser.

Ce contenu couvre les surfaces suivantes :

Fourmis : 170 à 340 m^2 (1 800 à 3 700 pi^2). Arroser abondamment le gazon avant le traitement.

Punaises des céréales : 275 m^2 (3 000 pi^2). Arroser abondamment le gazon avant le traitement. Répéter le traitement dans 7 à 10 jours au besoin.

Vers blancs : 200 m^2 (2 200 pi^2). Arroser abondamment le gazon après l'application ou appliquer pendant qu'il pleut. Appliquer entre fin juillet et début octobre.

LAISSER SÉCHER OU ATTENDRE 24 HEURES AVANT QUE LES ENFANTS ET LES ANIMAUX RETOURNENT DANS LA ZONE TRAITÉE.

PRÉCAUTIONS : GARDER HORS DE LA PORTÉE DES ENFANTS ET DES ANIMAUX DE COMPAGNIE. Ne pas permettre aux enfants ni aux animaux de compagnie de circuler sur la surface de traitement pendant l'application et avant que le produit pulvérisé n'ait entièrement séché. Nocif en cas d'ingestion, d'inhalation ou d'absorption cutanée. Éviter le contact avec les yeux, la peau et les vêtements et éviter d'inhaler le brouillard de pulvérisation. Bien se laver les mains après l'emploi et avant de manger, de boire, etc. Ne pas contaminer la nourriture, les ustensiles de cuisine, la nourriture de consommation animale ou l'eau. Ne pas utiliser dans la maison. Ne pas entreposer ni utiliser près de la chaleur ou d'une flamme nue. Toxique pour les abeilles et les oiseaux, les poissons et la faune, y compris le gibier d'eau.

PREMIERS SOINS : En cas d'ingestion, ne pas provoquer le vomissement. Consulter un médecin ou appeler un centre antipoison immédiatement. En cas de contact avec la peau, retirer les vêtements contaminés et laver à fond la région atteinte à l'eau et au savon. En cas de contact avec les yeux, rincer à grande eau de 10 minutes et consulter un médecin. Apporter le contenant, l'étiquette ou le nom du produit et le numéro d'homologation LPA lors de la visite chez le médecin.

RENSEIGNEMENTS TOXICOLOGIQUES : (selon le produit)

ÉLIMINATION : Ne pas réutiliser le contenant vide. Envelopper et jeter le contenant vide avec les ordures ménagères.

Appendix G

SAMPLE LABEL FORMAT FOR COMMERCIAL PRODUCT

ENGLISH VERSION

PRINCIPAL PANEL

Ready-to-use Insecticidal Contact Spray

For use in beef and hog barns and poultry houses

COMMERCIAL

READ THE LABEL BEFORE USING

GUARANTEE: Pyrethrin X%

REGISTRATION NO: XXXXX PEST CONTROL PRODUCTS ACT

Precautionary symbols and signal words (As Required)

Net Contents: 500 mL

Your Company
Your Postal Address
Your City, Your Province
Postal Code

SECONDARY PANEL

DIRECTIONS: Contact Spray. Kills crawling insects such as (name insects) in beef and hog barns. Define equipment to be used. Remove dirt and debris. Spray on floors, walls, ceilings and counters. Use approximately "x" L per 100 m^3. Insects must be contacted to be killed.

PRECAUTIONS: KEEP OUT OF REACH OF CHILDREN. Not for use on humans. May be harmful if swallowed or inhaled. Avoid contact with skin, eyes and clothing and avoid breathing spray mist. Wear chemical resistant gloves when applying product. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Do not remain in treated areas. Ensure proper ventilation after sealed areas have been treated. Do not contaminate food or feed. Do not contaminate feed or water troughs. Any treated surface that may contact food or feed products should be washed thoroughly with potable water after spraying and before reuse. Do not use in areas where bee-keeping equipment or supplies are stored. Product toxic to fish. Do not contaminate any body of water.

FIRST AID: If swallowed or inhaled, obtain medical attention or contact a poison control centre at once. If inhaled, remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. If on skin, wash thoroughly with soap and water. If in eyes, flush with clean water. If irritation persists, obtain medical attention or contact a poison control centre.

Take container, label or product name and PCP Registration Number with you when seeking medical attention.

TOXICOLOGICAL INFORMATION: (as appropriate)

DISPOSAL: Do not reuse container. Follow provincial instructions for any required cleaning of the container prior to its disposal. Make empty container unsuitable for use and dispose in accordance with provincial requirements. For information on the disposal of unused, unwanted product and the cleanup of spills, contact the provincial regulatory agency or the manufacturer.

NOTICE TO USER: This control product is to be used only in accordance with the directions on this label. It is an offense under the *Pest Control Products Act* to use a control product under unsafe conditions.

SAMPLE LABEL FORMAT FOR COMMERCIAL PRODUCT

FRENCH VERSION

PRINCIPAL PANEL

Insecticide de contact en aérosol

Pour bouveries, porcheries et poulaillers

(À USAGE) COMMERCIAL

LIRE L'ÉTIQUETTE AVANT L'EMPLOI

GARANTIE : pyréthrine X %

NO D'HOMOLOGATION XXXXX, LOI SUR LES PRODUITS ANTIPARASITAIRES

Symboles avertisseurs et mises en garde (selon le produit)

Contenu net : 500 mL

Nom de l'entreprise
Adresse postale
Votre Ville, Votre Province
Code Postal

SECONDARY PANEL

MODE D'EMPLOI : Aérosol de contact. Tue les insectes rampants tels que les (noms des insectes) dans les bouveries, les porcheries et les poulaillers. (Définir le matériel d'application à être utilisé.) Enlever la saleté et les déchets. Vaporiser sur le plancher, les murs, le plafond et les comptoirs. Utiliser environ x L par 100 m^3. N'est efficace que par contact avec les insectes.

PRÉCAUTIONS : GARDER HORS DE LA PORTÉE DES ENFANTS. Ne pas utiliser sur les humains. Nocif en cas d'ingestion ou d'inhalation. Éviter le contact avec la peau, les yeux et les vêtements et éviter d'inhaler le brouillard de pulvérisation. Porter des gants de caoutchouc résistant aux produits chimiques pour appliquer le produit. Bien se laver à l'eau et au savon après avoir utilisé le produit. Enlever les vêtements contaminés et les laver avant de les remettre. Ne pas rester dans les endroits traités. Aérer suffisamment les endroits clos après application. Éviter tout contact du produit avec la nourriture pour consommation humaine ou animale. Éviter de contaminer les mangeoires et les abreuvoirs. Laver abondamment à l'eau potable toute surface traitée susceptible d'entrer en contact avec les aliments de l'homme ou des animaux, après application du produit et avant de réutiliser la surface. Ne pas utiliser dans des endroits où sont entreposés des produits ou du matériel destinés à l'apiculture. Produit toxique pour les poissons. Éviter de contaminer toute étendue d'eau.

PREMIERS SOINS : En cas d'ingestion ou d'inhalation, consulter un médecin ou un centre antipoison immédiatement. En cas d'inhalation, amener la victime à l'air frais. Si elle ne respire pas, pratiquer la respiration artificielle, préférablement le bouche à bouche. En cas de contact avec la peau, laver abondamment à l'eau et au savon. En cas de contact avec les yeux, rincer abondamment à l'eau pure. Si l'irritation persiste, consulter un médecin ou communiquer avec un centre antipoison. Apporter le contenant, l'étiquette ou le nom du produit et le numéro d'homologation LPA lors de la visite chez le médecin.

RENSEIGNEMENTS TOXICOLOGIQUES : (selon le produit).

ÉLIMINATION : Ne pas réutiliser le contenant. Se conformer à la réglementation provinciale pour le nettoyage éventuel du contenant avant la mise au rebut. Après l'avoir rendu inutilisable, éliminer le contenant en se conformant à la réglementation provinciale. Pour toute information concernant l'élimination des produits non utilisés et le nettoyage des déversements, s'adresser à l'agence provinciale chargée de la réglementation ou au fabricant.

AVIS À L'UTILISATEUR : Ce produit antiparasitaire doit être employé strictement selon le mode d'emploi qui figure sur la présente étiquette. L'emploi d'un tel produit dans des conditions dangereuses constitue une infraction à la *Loi sur les produits antiparasitaires*.

Appendix H

SAMPLE LABEL FORMAT FOR RESTRICTED PRODUCT

ENGLISH VERSION

PRINCIPAL PANEL

Liquid Aquatic Herbicide Solution

RESTRICTED

READ THE LABEL BEFORE USING

GUARANTEE: active ingredient X%

REGISTRATION NO.: XXXXX PEST CONTROL PRODUCTS ACT

Precautionary symbols and signal words (As Required)

Net Contents 10 Litres

Your Company
Your Postal Address
Your City, Your Province
Postal Code

SECONDARY PANEL

NOTICE TO USER: This control product is to be used only in accordance with the directions on this label. It is an offense under the *Pest Control Products Act* to use a control product under unsafe conditions.

NATURE OF RESTRICTION: This product is to be used only in the manner authorized; contact local pesticide regulatory authorities about use permits that may be required.

RESTRICTED USE

GENERAL INFORMATION: Liquid Aquatic Herbicide Solution controls filamentous algae and certain other aquatic weeds in farm ponds, industrial ponds and lakes. Liquid Aquatic Herbicide Solution has no direct chemical action on aquatic vegetation. It filters wavelengths of sunlight, reducing the light intensity. The effect lasts as long as the water keeps its blue colour. Additional Liquid Aquatic Herbicide Solution can be applied when the colour of the water fades, or a second complete treatment can be made later in the season when the first new algae and weed growth is noticed.

It is recommended that the first treatment be made early in the growing season before algae and weed growth develops. When heavy vegetation is present at the time of treatment, the effect is slow, and dead vegetation may be present until fully decayed.

SHAKE WELL BEFORE APPLICATION

METHOD OF APPLICATION: Apply 750 millilitres (mL) of Liquid Aquatic Herbicide Solution per 1,000 cubic metres of water or the equivalent of 0.75 ppm of product. For volumes of water in large tanks or other containers, use 7.5 mL/10,000 litres. Treatment can be made from the shore without diluting; however, water may be added if a larger volume is required. Wind and current action causes intermixing with the entire water area. Re-apply as needed. May be poured through the ice.

PRECAUTIONS: KEEP OUT OF REACH OF CHILDREN. May be fatal if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear coveralls, boots and chemical resistant gloves when handling and applying product. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and discard or wash clothing before reuse. Do not use in water where loss of product can occur by water exchange or overflow, such as running streams or ponds with an outlet. Do not apply to water that will be used for drinking or other domestic purposes.

FIRST AID:

If Swallowed:

GET MEDICAL ATTENTION or contact a poison control centre. Induce vomiting.

If Splashed in Eyes:

Immediately flush eyes with plenty of water for at least 15 minutes and get medical attention or contact a poison control centre.

If Spilled on Skin:

Immediately remove contaminated clothing, including shoes, and wash skin with soap and plenty of water.

Take container, label or product name and PCP Registration Number with you when seeking medical attention.

TOXICOLOGICAL INFORMATION:

Active ingredient is a metabolic stimulant. Treat symptomatically.

DISPOSAL:

1. Rinse the emptied container thoroughly and add the rinsings to the spray mixture in the tank.
2. Follow provincial instructions for any required additional cleaning of the container prior to its disposal.
3. Make the empty container unsuitable for further use.
4. Dispose of the container in accordance with provincial requirements.
5. For information on the disposal of unused, unwanted product and the cleanup of spills, contact the provincial regulatory agency or the manufacturer.

SAMPLE LABEL FORMAT FOR RESTRICTED PRODUCT

FRENCH VERSION

PRINCIPAL PANEL

Solution herbicide aquatique

(À USAGE) RESTREINT

LIRE L'ÉTIQUETTE AVANT L'EMPLOI

GARANTIE : Matière active X %

N° D'HOMOLOGATION XXXXX, LOI SUR LES PRODUITS ANTIPARASITAIRES

Symboles avertisseurs et mises en garde (selon le produit)

Contenu net: 10 Litres

Nom de l'entreprise
Adresse postale
Votre Ville, Votre Province
Code Postal

SECONDARY PANEL

AVIS À L'UTILISATEUR : Ce produit antiparasitaire doit être employé strictement selon le mode d'emploi qui figure sur la présente étiquette. L'emploi d'un tel produit dans des conditions dangereuses constitue une infraction à la *Loi sur les produits antiparasitaires.*

NATURE DE LA RESTRICTION : Ce produit doit être employé strictement selon le mode d'emploi autorisé. S'informer auprès des autorités provinciales pour vérifier si un permis d'utilisation est requis.

À USAGE RESTREINT

RENSEIGNEMENTS GÉNÉRAUX : La solution herbicide aquatique élimine les algues filamenteuses ainsi que certaines autres mauvaises herbes aquatiques dans les étangs d'exploitation piscicoles, les réservoirs industriels et les lacs. La solution herbicide aquatique est dépourvue d'action chimique directe sur la végétation aquatique. Elle agit en filtrant les longueurs d'onde de la lumière du jour, réduisant ainsi l'intensité lumineuse. Cet effet dure tant que la coloration bleue de l'eau persiste. On peut rajouter de la solution herbicide une fois que cette coloration diminue, ou refaire une deuxième application plus tard dans la saison au moment de l'apparition des nouvelles algues ou mauvaises herbes.

Il est recommandé d'effectuer la première application tôt dans la saison, avant la croissance des premières algues ou mauvaises herbes. Si l'application est effectuée sur une végétation abondante, l'effet sera lent et les plantes mortes risquent de persister jusqu'à leur dégradation naturelle.

BIEN AGITER AVANT L'EMPLOI

MÉTHODE D'APPLICATION : Appliquer 750 millilitres (mL) de solution herbicide aquatique pour chaque 1 000 mètres cubes d'eau ou jusqu'à une concentration équivalant à 0,75 ppm du produit. Pour l'eau des grands réservoirs ou d'autres contenants, utiliser 7,5 mL/10 000 litres. Le traitement peut être effectué en versant le produit non dilué à partir du bord de l'eau; toutefois, il est suggéré de diluer le produit si un grand volume est nécessaire. La produit sera dispersé dans toute l'étendue d'eau grâce à l'action du vent et des courants. Faire une deuxième application au besoin. Le produit peut être versé à travers la glace.

PRÉCAUTIONS : GARDER HORS DE LA PORTÉE DES ENFANTS. Peut être fatal si ingéré ou absorbé par la peau. Éviter le contact avec les yeux, la peau ou les vêtements. Porter une combinaison, des bottes et des gants résistant aux produits chimiques lors de la manutention et de l'application du produit. Bien se laver à l'eau et au savon après avoir utilisé le produit et avant de manger, de boire et de fumer. Enlever les vêtements contaminés et les jeter ou les laver avant de les remettre. Afin d'éviter toute perte de produit, ne pas utiliser dans une étendue d'eau communiquant avec une autre ou susceptible de débordement (par exemple, dans les cours d'eau ou les eaux stagnantes ayant un déversoir). Ne pas utiliser dans l'eau potable ou servant un usage domestique.

PREMIERS SOINS :

En cas d'ingestion :

CONSULTER UN MÉDECIN ou communiquer avec un centre antipoison. Faire vomir.

En cas de contact avec les yeux :

Rincer immédiatement à grande eau durant au moins 15 minutes et consulter un médecin ou communiquer avec un centre antipoison.

En cas de contact avec la peau :

Enlever immédiatement les vêtements contaminés, y compris les chaussures, et laver au savon et avec beaucoup d'eau. Apporter le contenant, l'étiquette ou le nom du produit et le numéro d'homologation LPA lors de votre visite chez le médecin.

RENSEIGNEMENTS TOXICOLOGIQUES :

La matière active est un stimulant du métabolisme. Administrer un traitement symptomatique.

ÉLIMINATION :

1. Vider et rincer à fond le contenant. Ajouter l'eau de rinçage au mélange à pulvériser dans le réservoir.

2. Vérifier si un nettoyage supplémentaire du contenant avant son élimination est exigé en vertu de la réglementation provinciale.

3. Rendre le contenant vide inutilisable.

4. Éliminer le contenant conformément à la réglementation provinciale.

5. Pour toute information concernant l'élimination des produits non utilisés ainsi que le nettoyage des déversements, s'adresser à l'agence provinciale chargée de la réglementation ou au fabricant.

Appendix I

SAMPLE LABEL FORMAT FOR MANUFACTURING-USE PRODUCTS

ENGLISH VERSION

PRINCIPAL PANEL

2468 Acid

FOR MANUFACTURING, FORMULATING OR REPACKAGING

READ THE LABEL BEFORE USING

GUARANTEE: Active (present as acid) X%

REGISTRATION NO.: XXXXX PEST CONTROL PRODUCTS ACT

Precautionary symbols and signal words (As Required)

Net Contents: 25 kg

Your Company
Your Postal Address
Your City, Your Province
Postal Code
Telephone No.

SECONDARY PANEL

DIRECTIONS FOR USE:

To be used only in the manufacture of a pesticide which is registered under the PEST CONTROL PRODUCTS ACT. Read Technical Bulletin for formulation details.

FIRST AID:

IF SWALLOWED: Induce Vomiting. Get medical attention or contact a poison control centre immediately. If patient is unconscious, give him air.

IN CASE OF SKIN CONTACT:

Wash with plenty of soap and water.

IN CASE OF EYE CONTACT:

Flush eyes immediately with clean water for at least fifteen minutes and consult physician or contact a poison control centre.

TOXICOLOGICAL INFORMATION: Treat symptomatically.

PRECAUTIONS:

Keep out of reach of unauthorized personnel.

Avoid contact with eyes, skin and clothing. Harmful if swallowed. May cause eye or skin irritation. Do not inhale vapours. Wash well after handling and before eating, drinking and smoking. Wash contaminated clothing with soap and hot water before reuse. Do not wear contaminated shoes.

Do not contaminate irrigation water, lakes, streams or ponds by cleaning of equipment or disposal of wastes.

STORAGE:

Keep in original container during storage. Store product in cool, dry, well ventilated place away from seed, feed, fertilizer, or other pesticides. Keep away from fire or open flame, or other source of heat.

DECONTAMINATION AND DISPOSAL:

Canadian formulators using this product should dispose of unwanted active ingredient and containers in accordance with municipal or provincial regulations. For additional details and information on cleanup of spills, contact the provincial regulatory agency or the manufacturer.

NOTICE TO USER:

This control product is to be used only in accordance with the directions on this label. It is an offense under the *Pest Control Products Act* to use a control product under unsafe conditions.

NOTICE TO BUYER:

Seller's guarantee shall be limited to the terms set out on the label and subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product, and accepts the product on that condition.

SAMPLE LABEL FORMAT FOR MANUFACTURING-USE PRODUCTS

FRENCH VERSION

PRINCIPAL PANEL

Acide 2468

POUR LA FABRICATION, LA PRÉPARATION OU LE RECONDITONNEMENT

LIRE L'ÉTIQUETTE AVANT L'EMPLOI

GARANTIE : Matière active (sous forme d'acide) X%

N° D'HOMOLOGATION XXXXX, LOI SUR LES PRODUITS ANTIPARASITAIRES

Symboles avertisseurs et mises en garde (selon le produit)

Contenu net : 25 kg

Nom de l'entreprise
Adresse postale
Votre ville, Votre Province
Code Postal
Telephone #.

SECONDARY PANEL

MODE D'EMPLOI :

Ce produit doit être utilisé uniquement pour la fabrication de pesticides homologués en vertu de la Loi sur les produits antiparasitaires. Lire la fiche technique pour les détails concernant la composition.

PREMIERS SOINS : EN CAS D'INGESTION, provoquer le vomissement. Consulter immédiatement un médecin ou communiquer avec un centre antipoison. Si la personne est inconsciente, ne rien lui donner par la bouche. Si la personne ne respire plus, lui administrer la respiration artificielle immédiatement.

EN CAS DE CONTACT AVEC LA PEAU : Laver abondamment au savon et à l'eau.

EN CAS DE CONTACT AVEC LES YEUX : Rincer immédiatement et abondamment avec de l'eau pure durant au moins 15 minutes et consulter un médicin ou communiquer avec un centre antipoison.

RENSEIGNEMENTS TOXICOLOGIQUES: Administrer un traitement symptomatique.

PRÉCAUTIONS: Garder hors de la portée des personnes non autorisées.

Éviter tout contact avec les yeux, la peau et les vêtements. Nocif si ingéré. Peut causer l'irritation des yeux et de la peau. Ne pas respirer les vapeurs. Bien se laver les mains après avoir manipulé le produit et avant de manger, boire ou fumer. Laver les vêtements contaminés au savon et à l'eau chaude avant de les réutiliser. Ne pas porter les chaussures contaminées.

Lors du nettoyage du matériel ou de l'élimination des déchets, ne pas contaminer l'eau d'irrigation, les lacs, les cours d'eau ni les eaux stagnantes.

ENTREPOSAGE:

Garder le produit dans le contenant original pendant l'entreposage. Garder dans un endroit frais, sec et bien ventilé, loin des graines, de la nourriture, des engrais et d'autres pesticides. Garder éloigné du feu et de toute flamme, ainsi que des autres sources de chaleur.

DÉCONTAMINATION ET ÉLIMINATION :

Les fabricants canadiens du présent produit doivent éliminer les matières actives et les contenants en respectant la réglementation municipale et provinciale. Pour des renseignements détaillés concernant l'élimination ou le nettoyage des déversements, s'adresser à l'agence provinciale chargée de la réglementation ou au fabricant.

AVIS À L'UTILISATEUR

Ce produit antiparasitaire doit être employé strictement selon le mode d'emploi qui figure sur la présente étiquette. L'emploi d'un tel produit dans des conditions dangereuses constitue une infraction à la Loi sur les produits antiparasitaires.

AVIS À L'ACHETEUR :

La garantie du vendeur est limitée et soumise aux conditions exprimées sur l'étiquette de sorte que l'acheteur assume les risques corporels ou matériels que l'utilisation ou la manipulation du produit peuvent entraîner et accepte celui-ci à cette condition.

Appendix J

Definitions and Codes for Formulation Types

Code	Name	Definition
DU	DUST OR POWDER	dry material composed of active ingredient(s) and non-active ingredients. No requirement for further dilution before application. Insoluble in water and containing no wetting or dispersing agent(s). Material will float on water. Particle diameter usually less than 250 microns. Dusts or powders that contain wetting or dispersing agent(s) belong in WP code; if they are soluble, they belong in SP code.
DF	DRY FLOWABLE	see wettable granules (WG).
DV	DEVICE	any article, instrument, apparatus, or contrivance that, by itself or in conjunction with a control product, is used as a means to control pests.
EC	EMULSIFIABLE CONCENTRATE OR EMULSION	clear solution of active ingredient(s) in solvent(s) with emulsifier(s) for dilution in water. Also cloudy dispersion of one liquid in another (oil in water, or water in oil) with active ingredient(s) in either phase to form a true emulsion. Includes most lotions.
GR	GRANULAR	solid mixture of any dry, free-flowing water insoluble particles (usually larger than 500 microns and smaller than 2 mm in diameter) composed of active ingredient(s) and non-active ingredient(s). Sand-based products are included in this code.
IF	IMPREGNATED FABRIC	fabric(s) or fibre(s) impregnated with active ingredient(s), such as repellent-impregnated jackets, repellent-impregnated towelettes, herbicide wick, and pet collars, that employ a material impregnated with the active ingredient.
LI	LIQUID	clear liquid composed of one or more active ingredient(s) (100% active), or with small amounts of production non-active ingredients, fire suppressants, flame inhibitors or indicators (97-100% active). Includes volatile products packaged as a liquid under pressure for release as a gas.
LO	LIVE ORGANISM	a life form capable of reproduction, e.g., bacteria, insects, fungi, mites, nematodes, virus and *rickettsia*-like organisms.
MS	MICROCAPSULE SUSPENSION	a suspension in which the solid particles consist of the active ingredient(s) within microcapsules that allow a slow release of the active ingredient(s).

Code	Name	Definition
PA	PASTE	a grease or ointment composed of active ingredient(s) and semi-solid non-active ingredient(s).
PE	PELLET	dilute, preformed solid mixture of active ingredient(s) in the form of spheres, ovals, or cylinders. Particles should have no dimension less than 2 mm.
PP	PRESSURIZED PRODUCT	may be a liquid, solid, gas, active ingredient(s) and non-active ingredient(s), or mixture thereof discharged by a propellant force of liquefied and/or non-liquefied compressed gas, usually from a disposable type of dispenser through a valve. Includes aerosols, pressurized sprays, pressurized foams and pressurized dusts. Does not include formulations dispersed by a pump mechanism.
PT	PARTICULATE	dry active ingredient(s) and non-active ingredient(s) in the form of large particles, but not fitting the definitions of a granular or pellet formulation. Most products in this category are rodent or insect baits, formulated on sugar, whole or chopped grains, or other coarse material.
SG	SOLUBLE GRANULES	solid mixture as in GR, except that the granules are soluble in water.
SN	SOLUTION	clear liquid composed of active ingredient(s) (liquid or solid) dissolved in solvent(s).
SO	SOLID	material in solid form composed of active ingredient(s) and/or non-active ingredient(s). Includes all solid materials formulated as blocks, flakes, cartridges, balls, crystals or other formulations that do not come within the definitions of other dry products.
SP	SOLUBLE POWDER	dry material as in DU, except that it is soluble in water.
SR	SLOW-RELEASE GENERATOR	a combination of a solid base material, for example, PVC resin, and a volatile liquid or solid toxicant(s), that slowly emits the toxicant(s) as a vapour, e.g., vapour strips.
SU	SUSPENSION	cloudy liquid composed of solid active ingredient(s) suspended in a liquid phase for further dilution with similar liquids, or ready-to-use. Includes aqueous suspensions, paints, and flowable concentrates.
TA	TABLET	solid active ingredient(s) or mixture of active ingredient(s) and non-active ingredient(s) preformed into a small block or sphere.

Code	Name	Definition
WD	WATER DISPERSIBLE GRANULES	see wettable granules (WG)
WG	WETTABLE GRANULES	a granular formulation, possibly in dry flowable form, that forms a suspension in water. Includes water dispersible granules - a granular formulation designed to be dispersed in water for application as a spray.
WP	WETTABLE POWDER	dry material composed of active ingredient(s) and non-active ingredient(s), including wetting or dispersing agent(s), for dilution (usually in water) to form a suspension.

Appendix K

List of Forms Referenced in the Registration Handbook

Application for Acceptance in the Pesticide Own-Use Import Program, HC/SC 6004 (97/01)

Application for New or Amended Registration, HC/SC 6005 (97-01)

Application for Registration of Private Label Product (based on registered initial product), HC/SC 6012 (01/97)

Application for Registration Renewal, HC/SC 6000 (06-96)

Application for Research Permit, HC/SC 6006 (96/01)

Declaration by Importer of Control Products, HC/SC 6018 (04-98)

Fee Form, HC/SC 6011 (06-98)

Notification of Pesticide Research, HC/SC 6008 (97/09)

Product Specification Forms, HC/SC 6003 (10-95)

Note: These forms are subject to revision and a revised form will be reissued under a new number. This Appendix will be updated as required to reflect the current versions of these forms. Please use only *original* and *current* forms; photocopies or outdated forms are not acceptable.

Appendix L

Acronyms Used in the Registration Handbook

AMC	Agency Management Committee
ATIA	*Access to Information Act*
CAS	Chemical Abstracts Services
CBI	Confidential Business Information
DIN	Drug Identification Number
EC	European Commission
EMAC	Economic Management Advisory Committee
EP	end-use product
EPA	Environmental Protection Agency
FDA	*Food and Drugs Act*
GLP	Good Laboratory Practice
HPA	*Hazardous Products Act*
ICPMAC	Interim Canadian Pest Management Advisory Council
IMEP	Importation for Manufacturing and Export Program
IPM	Integrated Pest Management
ISO	International Standards Organization
ISP	integrated system product
IUPAC	International Union of Pure and Applied Chemistry
LOC	letter of confirmation
MA	manufacturing concentrate
MP	manufacturing-use product
MRL	maximum residue limit
MSDS	Material Safety Data Sheet
MUPP	Minor Use of Pesticides Program
OECD	Organisation for Economic Co-operation and Development
OUI	Pesticide Own-Use Import Program
PCP	pest control product
PCPA	*Pest Control Products Act*
PCPR	Pest Control Product Regulations
PGR	plant growth regulator
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRDD	Proposed Regulatory Decision Document
PRR	Pesticide Registration Review
PSCD	Product Sustainability and Coordination Division
TDGA	*Transportation of Dangerous Goods Act*
TGAI	technical grade of active ingredient
TPD	Therapeutic Products Directorate
URMULE	User-Requested Minor Use Label Expansion
URMUR	User-Requested Minor Use Registration
WHMIS	Workplace Hazardous Materials Information System